Reamed nailing of humeral fractures : clinical and biomechanical aspects

REAMED NAILING OF HUMERAL FRACTURES

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PROEFSCHRIFT

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Contents

General Introduction

Over the past hundred years the treatment of fractures and especially of humeral fractures has changed dramatically. At the beginning of the twentieth century humeral fractures were treated mainly non-operatively. The principles of treatment were reposition of the fracture, immobilisation and, after fracture healing, revalidation. The different steps in fracture treatment were dealt with sequentially. For complete immobilisation thoraco-brachial casts and/or bandages had to be used. Due to long immobilisation, extensive joint function impairment could be expected; on the other hand due to insufficient immobilisation non-union was one of the most common complications. The introduction of the hanging cast improved the results of non-operative treatment because it created better alignment of the fracture and allowed some function in the shoulder joint.

Operative treatment in general was reserved for non-unions. Early attempts to develop plates and intramedullary devices for osteosynthesis scattered on the lack of proper materials. Ivory and bone pegs led to early resorption of those pegs and the metal alloys used caused bone resorption. Eventually these techniques were given up.

During the interbellum Gerhard Küntscher developed the intramedullary nailing technique, which formed the base of the nailing techniques we still know today. According to Küntscher all long bones were suited for intramedullary osteosynthesis. The complication rate in the hands of other, less experienced surgeons, especially with humeral and tibial fractures, eventually led to the classic publication of Böhler against the operative treatment of humeral fractures.

In the fifties and sixties the AO/ASIF developed the principles of modern plate osteosynthesis based on the ideas of Lambotte and Danis. Reconstruction of anatomy in order to restore function, absolute stability and "primary bone healing" were the basic principles. The research based philosophy of the AO/ASIF and intensive teaching made the use of plate osteosynthesis in the treatment of long bone fractures become generalised. Reluctantly at first because of the significant number of complications such as radial nerve palsy and non-unions, but after having gained more experience, the plate osteosynthesis of humeral fractures became the standard.

The success of interlocking nailing developed by Klemm and Schellman for tibial and femoral fractures in the seventies combined with the concept of "biological osteosynthesis" conceived in the eighties, gave rise to the development of an interlocking humeral nail. Bridging comminutive fractures with the plate in order to preserve soft tissues and bone vascularisation instead of meticulous anatomical reposition with stable fixation of all fragments was advised. An intramedullary nail appeared to fit well in this concept, especially for the humerus. The interlocking bolts provided for rotational and axial stability and made extensive reaming as for the Küntscher nail unnecessary.

After the introduction of the Humeral Locking Nail® by Seidel other humeral implants became available each with their own characteristics and operative technique: reamed or unreamed, antegrade or retrograde introduction, sometimes with compression. As always a new technique generates its own specific complications.

Antegrade introduction caused problems with shoulder function. With retrograde introduction iatrogenic fractures were typical complications. On the other hand radial nerve palsy and infection could be reduced significantly.

Reaming allows the introduction of a thicker, more stable implant with stronger locking bolts. A very important advantage is that reaming provides an internal cancellous bone graft.

In this thesis the concept of reamed nailing for the treatment of injuries of the humerus is evaluated both clinically and biomechanically. This concept has been evaluated in a multicentre study in the Netherlands with use of the Telescopic Locking Nail® (TLN®). Furthermore its use in specific indications as acute fractures and non-union has been studied. With a growing incidence of elderly patients in our society the amount of humeral fractures will grow also, therefore humeral fractures in the above 60s are evaluated as a separate group. A biomechanical study compares the concept of a straight reamed compression humeral nail with its unreamed counterpart, the Unreamed Humeral Nail® (UHN®). In vitro bending and torsion tests with and without compression after implantation in human cadaveric humeri have been carried out.

Different humeral nails and treatment concepts exist. Rather than to promote one implant or technique in the treatment of humeral fractures, the aim of this thesis is to provide the surgeon with objective information on reamed IM nailing of the humerus. This should help him to decide which technique to use for treatment of humeral fractures and delayed or non-unions. It is therefore to the surgeon, provided he is familiar with the routine of intramedullary nailing or plating, to decide which technique he will favour, both taking into account the patient's needs and his own skills.

CHAPTER 1

History of Humeral Nailing

Wood, ivory and bone

The treatment of fractures and especially humeral fractures always has been non-operative. Only in the case of non-union operative intervention was indicated.

Intramedullary nailing of the long bones already has been practiced by the Aztec in Mexico. Apart from traction and fixation techniques for the treatment of fresh fractures, the conquistadors in the 16th century reported the use of resinous wooden pegs introduced intramedullary for the treatment of non-unions of long bones [after 7, 23].

In Europe operative treatment of humeral non-union with wires has been mentioned as early as 1775. The first real treatment with wire loops was attributed to Rodgers in 1827 [after 3]. Intramedullary techniques became in use in the 19th century. Dieffenbach in 1848 and von Langenbeck (1850) used ivory "pegs" in the treatment of long bone fractures. Both also used metal nails in the treatment of femoral neck fractures. Heim in Kiel (1875) experimented also with this technique. It was used clinically by von Volkmann, Bardenheuer (1875), Socin (1879) and Bruhns (1879). Originally only non-unions were operated on. In 1886 Bircher reported on the use of ivory pegs in the treatment of fresh fractures [after 3, 23, 33]. Nicolas Senn (1893) advised the use of animal bone [after 3]. These "pegs" were introduced through the fracture in an open technique. Lejahr (1902) and Rissler improved the technique by developing long, tight fitting ivory nails that filled the medullary canal completely (the word "nail" is here in order in contrast to the "pegs" used earlier) [25]. It became widely used till about 1930, when it finally was given up. Lack of proper anti-sepsis and loss of reduction and stability, due to early resorption of these implants, resulted in infection and non-union [after 23, 33, 28].

Metallic alloys

The bad experiences with these biodegradable implants made surgeons turn to the use of metallic devices. Nicolaysen (1897), Delbet (1906) and Lambotte (1907) used steel wires and screws intramedullary. Hey Groves is considered the father of the intramedullary osteosynthesis. He used an open technique with introduction of the nails through the fracture. He did describe also nailing through the greater trochanter of the femur and the greater tubercle of the humerus [13, after 44]. The biggest problem of these pioneers in osteosynthesis was the reaction of bone to the metals used. Due to corrosion, bone resorption occurred round the plates and nails, leading to loosening. According to Arbuthnot Lane in 1893 who experimented with metal plates and screws this was caused by a bad surgical technique: "...rarefying osteitis means in plain English dirty surgery..." (quoted by [44]). Venable et al. however could demonstrate the resorption of bone through electrolysis caused by the interaction of bone and body fluids with alloys used in that time [after 28, 33, 43]. Osteosynthesis with metallic implants therefore proved to be unreliable and became not generally accepted. Operative treatment of fractures was left and considered as not indicated. So the period after the first World War became "the era of the high priests of traction and plaster cast such as Böhler in Vienna and his Liverpool counterpart Watson -Jones" [40]. It was only after the development of biologically inert metals like vitalium that the technique of osteosynthesis had a revival. Muller-Meernach (1933) used laminated rods, Joly (1935) multiple steel rods. The use of intramedullary splinting with Kirschner wires was advocated by Danis (1937) and Lambrinudi (1940). The Rush brothers (1936) developed flexible pins. Stability depended on the recoil of the pre-bended pins rather than on the tight fit in the medullary canal. But these methods never were mechanically efficient and "it was not until wide nails -fully engaging the medulla of the bone- were re-introduced, that the technique commanded respect" (quoted from [44]).

Intramedullary nails

Küntscher developed the technique of intramedullary nailing, as it is still known today (Figure 1-1). He himself stated that he was inspired by the technique of nailing femoral neck fractures with a three-flanged nail - which created stability through impingement in the cancellous bone of the femoral head - and his own experimental observations

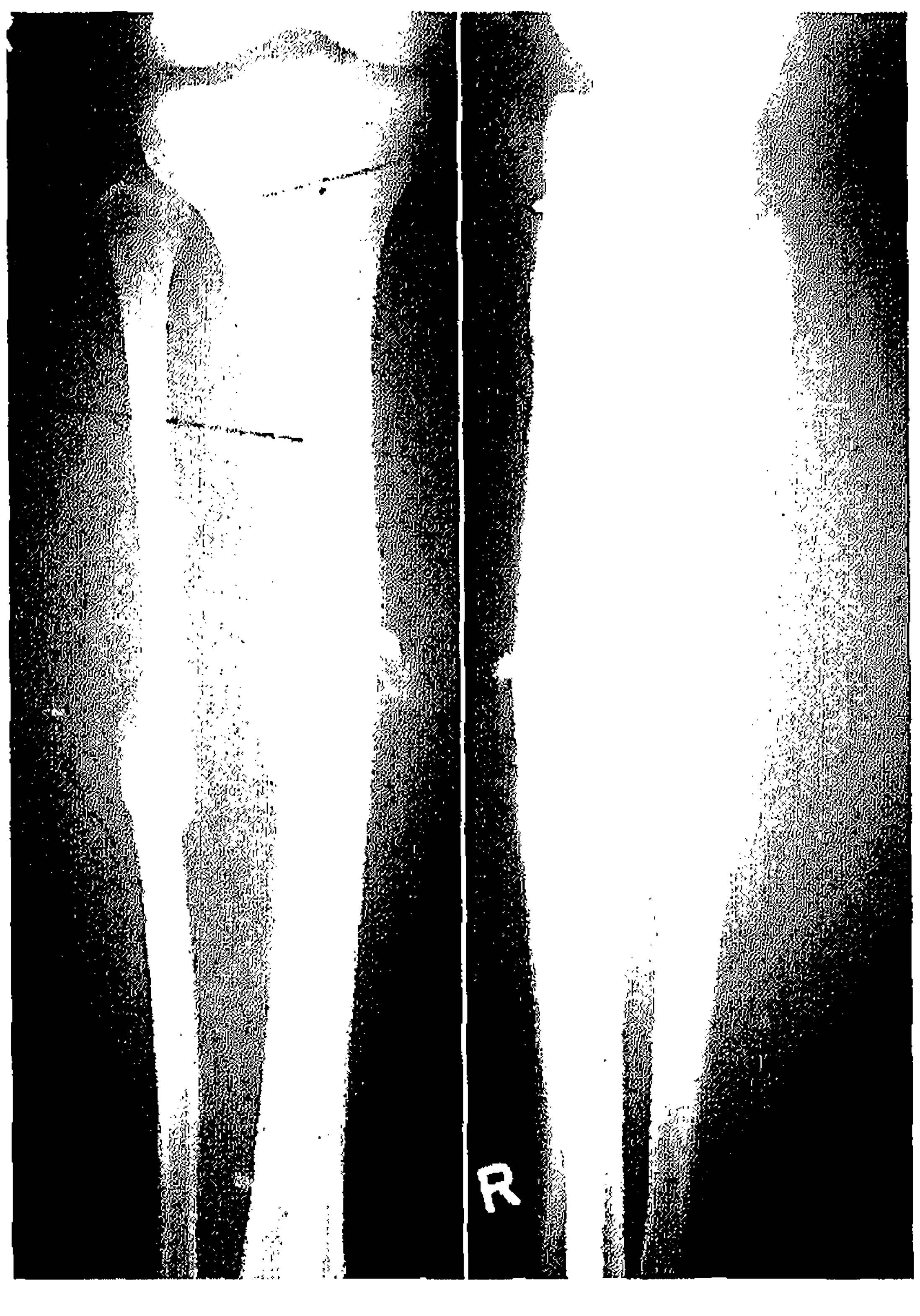

Figure 1-1. Tibial fracture treated with a Küntscher nail

Figure 1-2. Humeral shaft fracture treated with retrograde introduced Küntscher nail.

on callus formation [23, 24, 28]. Indirect reposition and introduction away from the fracture site, not to disturb the fracture hematoma, followed by early functional treatment, are the principles still used today. The technique became generalised in the treatment of long bone fractures. Even Böhler, who was renown for non-operative treatment of fractures and was convinced that the medullary canal was not to be interfered with, adapted the new technique: "Küntscher´s intramedullary nailing is the method of the future" [2, 20]. Küntscher and his allies steadily developed new implants and looked for new indications. Techniques of humeral nailing, ulnar and radial nailing, arthrodesis and corrective osteotomies have already been described by Küntscher and his co-workers (Figure 1-2).

The less good results in the hands of less experienced surgeons however gave the intramedullary nailing technique a bad name. A survey done by Rehm in several large hospitals in Germany showed that part of the trauma departments did not apply the proper technique with intramedullary nailing [34]. Both for tibia and humerus rotational stability appeared to be insufficient and additional external fixation often was necessary. In the case of humeral fractures also axial stability was a concern. The weight of the arm alone often was enough to cause distraction. Küntscher himself was aware of the problem and advised to use "other measures in addition to the nail" [28]. A split removable plaster cast was used to protect the osteosynthesis and allow intermittent exercises. Maatz described a technique in which the cast is divided in the transverse plane and fixed with rubber bands. This created a kind of compression and prevented the fracture to distract axially by the weight of the arm. Later Maatz would develop the "spring nail" which was a combination of a nail with a spring and compressed the fracture [25, 28]. He achieved good results but the complexity of the technique led to failures in the hands of less experienced surgeons [25]. Later the idea of compression nails would be developed further.

Due to the high complication rates with tibial and humeral nailing, Böhler, though at first an enthusiastic user of intramedullary nailing, stated: "a great tragedy has befallen mankind, intramedullary nailing!" At last he forbade nailing in the hospitals that resorted under his direction except for the treatment of femoral fractures [25, 28].

The first "locking" nail was the implant developed by Modny and Bambara in 1953 [23, 32]. They provided a cruciate nail with holes over the entire length. The four flanges provided for rotational stability. The holes were meant for levering the nail in position after open introduction, and for cross fixation with screws. Sometimes the medullary canal had to be enlarged. For this a specific reamer was foreseen. This nail could also be used as a "classic " intramedullary nail to be introduced by a closed technique. Based on this concept Halloran provided a nail with slotted holes. This would stimulate ingrowth of vascular structures stimulating bone healing [12].

Plate osteosynthesis was still in use after the Second World War but declining. Non-operative treatment of fractures especially humeral fractures as practiced by Böhler and Watson-Jones had been developed to that high standards that their results could hardly be improved by operative treatment. Operative fracture treatment became reserved for femoral shaft and femoral neck fractures. Intramedullary techniques proved much more efficient here compared to plate osteosynthesis [40].

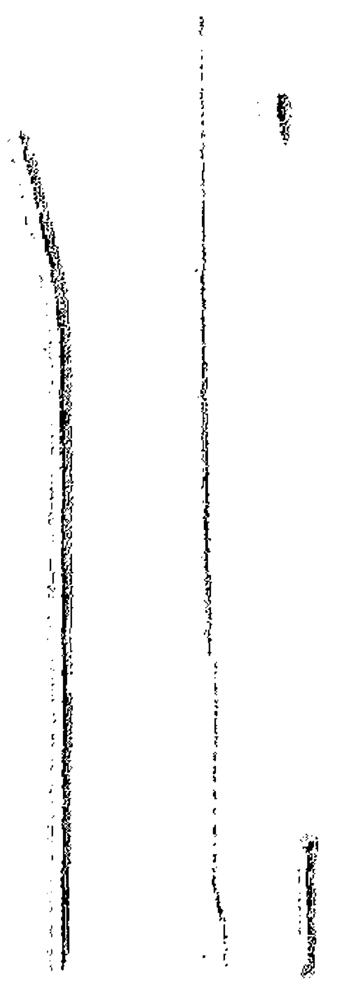

Figure 1-3. Kaessmann nail

Meanwhile the foundation of the AO in 1958 led to the introduction of the principles of absolute stability and primary bone healing in the treatment of fractures. Principles already recorded by Lambotte in 1913 and Danis in 1949 [40]. Kaessmann combined these principles with the technique of intramedullary nailing. He combined a modified Küntscher nail with a thin inner nail (Spanndorn) that was fixed to the bone by a transverse screw distally and to the nail proximally with a collar lock after having compressed the system (Figure 1-3).

The Kaessmann nail was available for femur, tibia and humerus (Figure 1-4). Interfragmentary compression enhances stability in fractures. Consequently extensive reaming was no longer necessary and thinner nails could be used. Indications could be extended to more proximal and distal fractures [16,17,18,42]. Other implants followed. Huckstep improved the concept of Modny. He developed a titanium nail with square cross-section and holes over the total length. An aiming device allowed easy introduction of locking screws. He also foresaw a compression device. The nails could be used for tibial, femoral and humeral fractures [14,26].

Figure 1-4. Humeral fracture treated with Kaessmann nail

Hackethal developed a technique with elastic nails that could be introduced antegrade and retrograde in every long bone. Introduction of a rigid nail through an excentric portal as with the humerus and tibia, is not easy; especially with fractures in the proximal third. In this case anatomical reduction of the fracture is not always feasible. Flexible nails are easier to introduce then. To provide for rotational and axial stability the medullary canal has to be filled completely. In this way the nails are jammed and cannot dislocate. Despite this, rotational stability is poor and if one nail dislocates, the complete osteosynthesis becomes unstable. As a minimal invasive technique it still has its followers[11].

The strong organisation of the AO with its scientifically based philosophy and supported by systematic teaching courses and standardisation of techniques and materials however led to a widespread use of plating in Europe and the rest of the world[40]. This gave also new impulses to the development of intramedullary nailing. Research, cooperation with engineers and critical reflexion on indications and comparison with other techniques led to improvements in implants and technique [25].

At the end of his life Küntscher developed the "Detensionsnagel" (detensor) for the treatment of comminutive femoral fractures (Figure 1-5). This concept was further developed into the intramedullary "locking nail" (Verriegelungsnagel) by Klemm and Schellman followed by Grosse and Kempf in the seventies [21,22]. This caused a revival of the intramedullary techniques in fractures of tibia and femur. At first mainly used by Klemm in treatment of infected femora with bone defect, also tibial nails were [illegible] the use of better materials made it the standard for the treatment of fractures of the leg. Not only active exercises were possible but also immediate weight bearing was allowed. Even the AO accepted this technique and adapted it to its philosophy developing their own implants. This however not until 1986 when the "universal nail" was introduced [40].

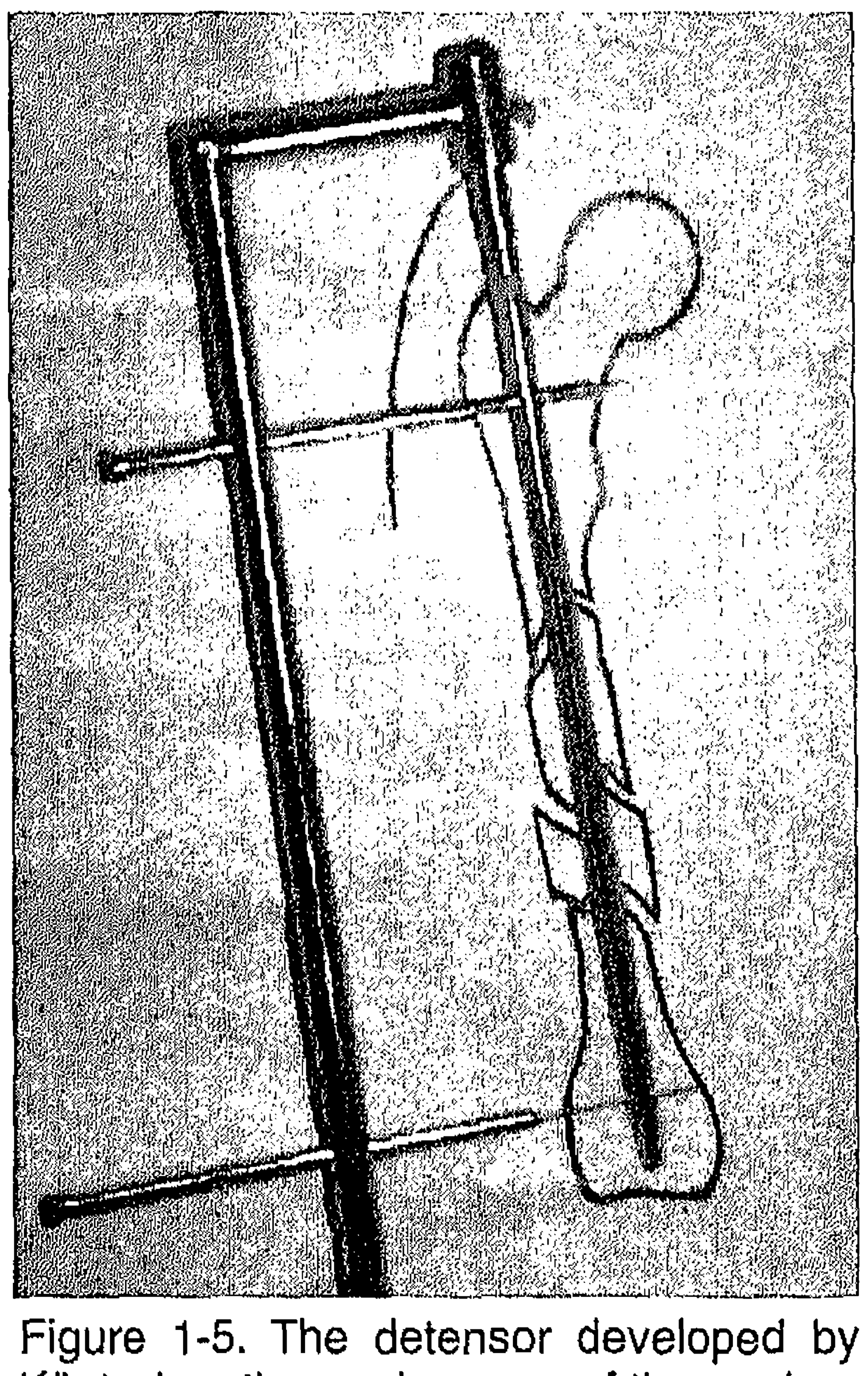

Figure 1-5. The detensor developed by Küntscher, the predecessor of the modern locking nails.

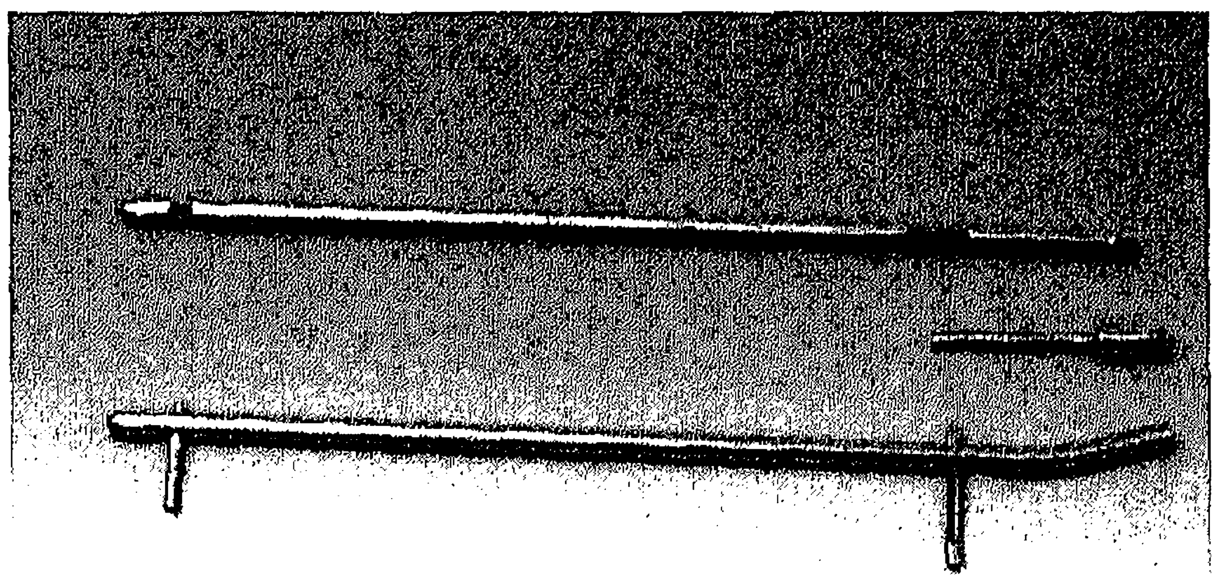

Figure 1-6. The Derweduwen nail for humerus (above) and tibia (below). In the middle the compression screw.

Ritter with modified AO-nails and Mittelmeier with a self-designed nail, studied the effect of compression on intramedullery nailing. Axial set screws were used to exert compression and enhance stability of intramedullary nails especially if used with transverse fractures. According to their work due to distortion of the nails introduced and low interference between locking bolts and nail, rotational forces could not always be excluded. Compression was seen as a tool for extra-stability, e.g. in the case of non-unions. It was not to compare with compression as described by the AO/ASIF, which promoted compression and absolute stability to allow primary bone healing [30, 31,36,37]. The Belgian Derweduwen also had developed a locking nail for femur, tibia and humerus. A special feature was the possibility of axial compression applied through an axial setscrew [6] (Figure 1-6).

A Humeral Interlocking Nail

Until then the humerus preferentially was treated non-operatively. The technique of functional bracing developed by Sarmiento proved to be a good alternative for plate osteosynthesis with its risks for radial nerve paralysis, non-union and infection.

The succes of and experience gained with modern locking nails however led directly to the development of intramedullary nails to be used in other long bones, especially the humerus. Indirect introduction of an implant avoiding large incisions and possible radial nerve palsy would be an ideal technique for the humerus. In that time also the concept of biological osteosynthesis was introduced. Meticulous anatomical reconstruction of every little fragment was no longer considered necessary and even obsolete. Bridging fractures with plates to preserve vascularisation and soft tissues became the new concept. Seidel from Hamburg presented his Humeral Locking Nail® (SN) in 1985. This was the first interlocking nail for the humerus to be used on a large scale. It is a 9 mm nail to be introduced antegrade. Proximal locking was done through an aiming device, distal locking used a system of flanges to be spread after introduction of a screw in the distal part of the nail (Figure I-7). Reaming was necessary because of the 9 mm diameter but also to create enough space in the medullary canal to allow the flanges to be spread. The principle of a minimal invasive

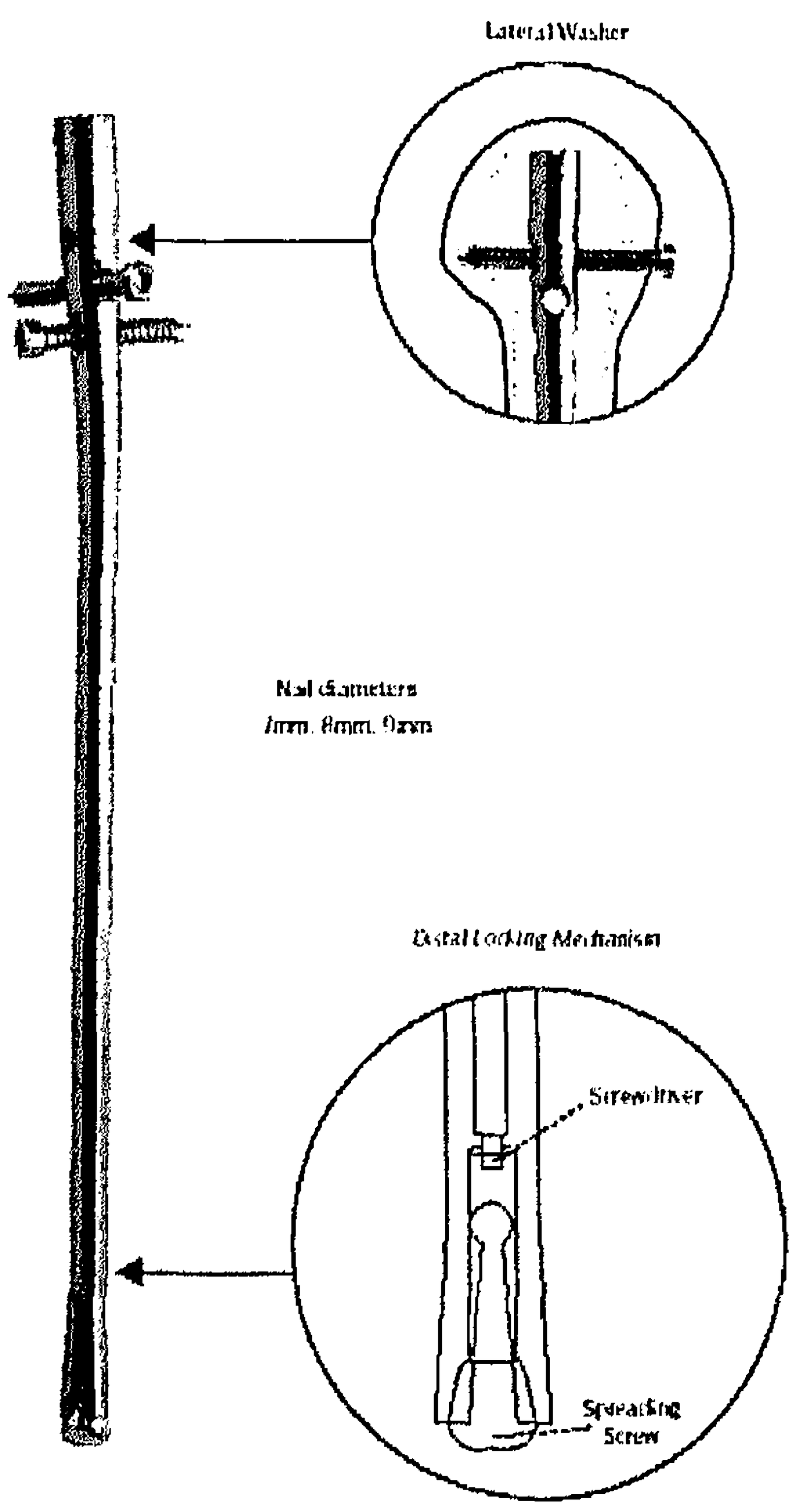

Figure 1-7. The Seidel Humeral Locking Nail with its specific locking technique (© Stryker Company)

technique as alternative for the plate with its extensive dissections and risk of radial nerve damage created great enthusiasm at first supported by reports of good results [19, 35, 41].

The large diameter requiring reaming, the antegrade introduction damaging the rotator cuff and the lack of rotational stability because of an insufficient distal locking system caused great concern in other hands. As a consequence other implants were developed and other ways of introduction looked for. The Russell-Taylor Nail® (RT) (Smith and Nephew-USA) for the humerus was specifically developed for antegrade introduction but retrograde introduction appeared to be possible also. Rommens et al. used the Russell-Taylor® nail in the retrograde way to prevent rotator cuff damage with good healing and functional results [5, 39]. His experience with this nail led to the development of the Unreamed Humeral Nail® (Synthes®-Bettlach, Switzerland) (Figure 1-8). This implant was developed specifically f et grade int oduction b ' ant - grade nailing was possible. Application of compression was also possible. Healing and functional results were good, with a minimun of complications[1, 38]. Lin et al. developed also a specific nail for retrograde introduction[27]. The Telescopic Locking Nail® developed by Stapert is a universal nailing system for humerus, tibia and femur. For the humerus both retro and antegrade nailing are possible. I' was used with success in the Netherlands and Germany (Figure 1-8).

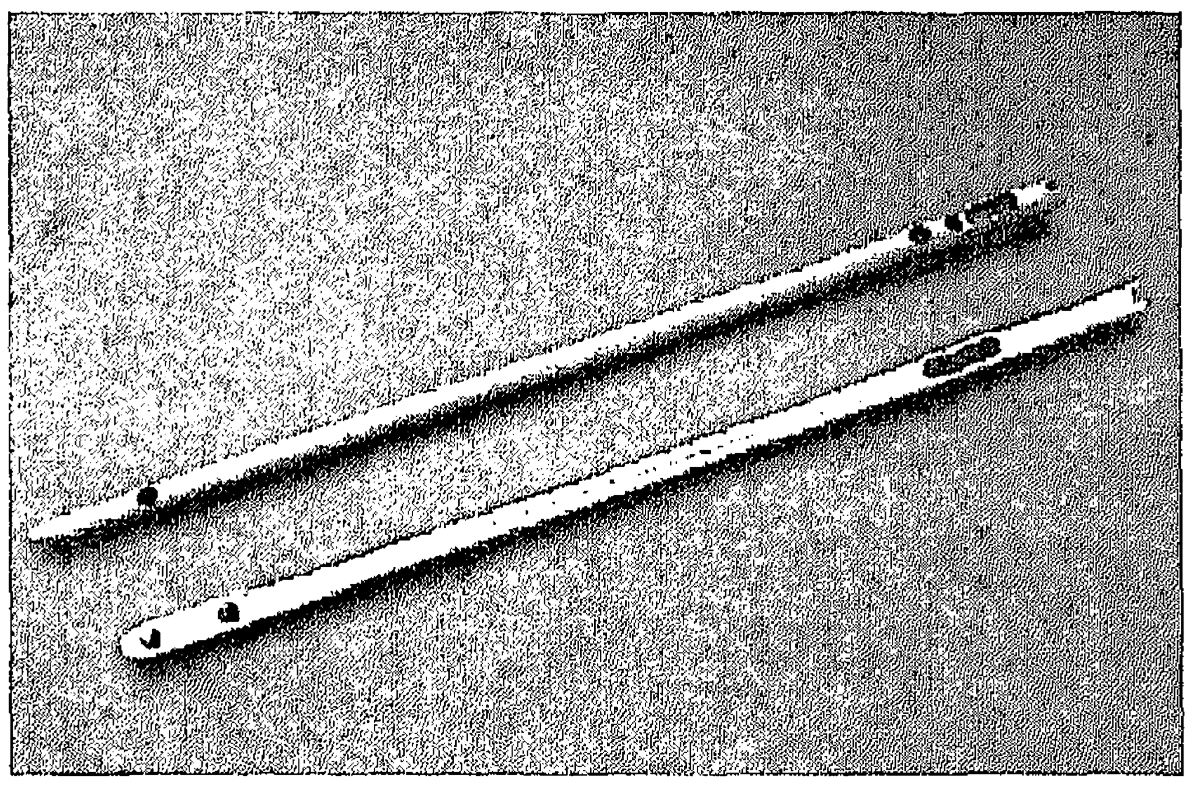

Figure 1-8 UHN® and TLN®

A comparable nailing system was the Intramedullary Compression Nail®. Both systems were developed as a total package offering a nail for every long bone including the humerus and provided the possibility of compression [4, 9, 10]. Other developments are the Vincenzi-Marchetti Nail®, which combined the classic nail with elastic nailing and the Fixion® nail which is an expandable nail that impinges itself in the medullar canal without the use of locking bolts [29, 8, 15, 45].

All these nails follow the same basic philosophy once stated by Küntscher: indirect reposition of fracture, introduction of the nail away from the fracture and immediate exercises and weight bearing post-operatively. Each nail has or had its own specific features and led generally to good healing and functional results. Infectious complications and radial nerve palsy were substantially less than with a plate. Non-union appeared to be equal or some what higher than with the plate. However, new implants inevitably lead to new complications. Typical for nailing are iatrogenic fractures caused by nail introduction. This is partly due to technical errors and inexperience with the technique but the nail design might also play a role. It is in the last decade of the past century that humeral nailing has been developed to what it is now, leading to a wide acceptance and use nowadays. Experiences made in the past and the never lasting urge of clinicians and industry led to development of new and better implants for the benefit of the patient. These are the exponents of the experiences made in the past by pioneers like Küntscher. The ideal humeral nail does not exist (yet). The same urge which led to the development of the implants we know today, eventually will deliver the optimal humeral nail.

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CHAPTER II

Development of a Reamed Locking Nail for the Humerus

The Telescopic Locking Nail®

The concept of the Telescopic Locking Nail® presents a universal nailing system for femur, tibia and humerus. This concept would diminish the stock of intramedullary implants dramatically as the same nail was to be used for every long bone. The following conditions formed the base of this implant:

1) Cyclic dynamic loading should be possible, maintaining rotational and angular stability. At the same time static fracture fixation and compression should be possible.
2) The nail should behave like an internal fixator and not rely on intramedullary impingement for stability.
3) The diameter of the nail should allow minimally reamed or unreamed introduction.
4) Early weight bearing should be possible without implant failure.
5) Stocks of intramedullary nails should be reduced in using only one nail for the treatment of all long bones.
6) The same instrumentation for all implants should be used.

The Telescopic Locking Nail® consists of a straight nail with distally two locking holes and proximally a slot of 2.5 cm (Figure 2-1). An outer tube with 2 locking holes that correspond with the slot passes over the proximal end of the nail (Figure 2-2). After interlocking, the nail is rotationally stable but because of the slot, remains dynamic (Figure 2-3). Under weight bearing the fracture undergoes cyclic dynamic loading and axial compression, which promotes stability and fracture healing. With different axial setscrews different constructs can be made: compression, distraction, static and dynamic configurations are possible, depending on fracture type or indication (Figure 2-4). Another advantage of this system is peroperative lengthening of the nail. After retraction of the sliding lock in the aiming device, the inner nail can slide over 2,5 cm. This makes exact positioning of the nail tip possible and allows the treatment of very distal shaft fractures (Figure 2-5).

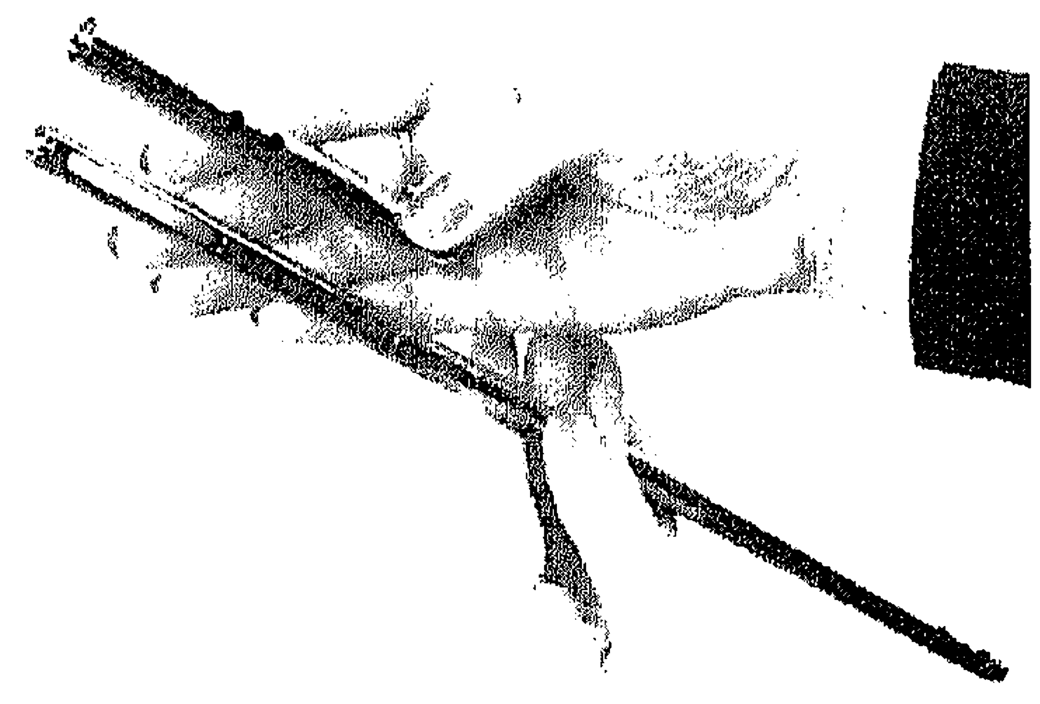

Figure 2-1. The inner nail of the TLN® and the telescope. The oblong hole and the corresponding round holes of the telescope are clearly visible

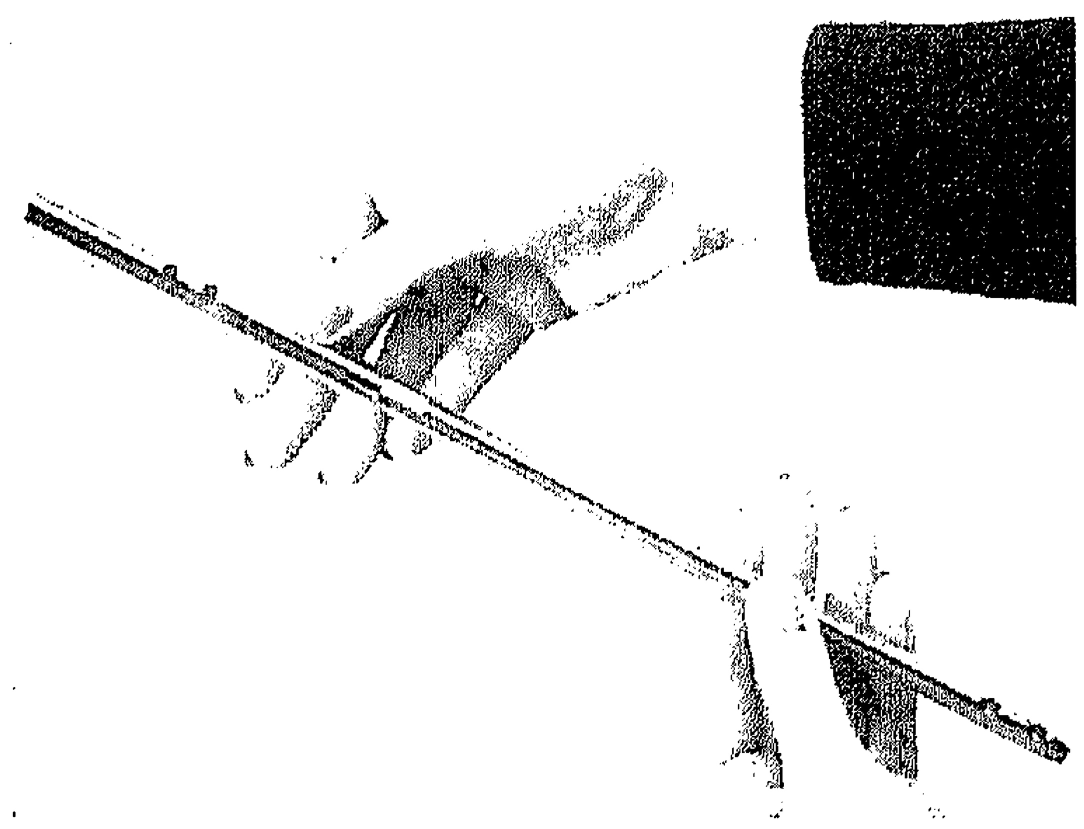

Figure 2-2: The telescope is passed over the proximal end of the nail.

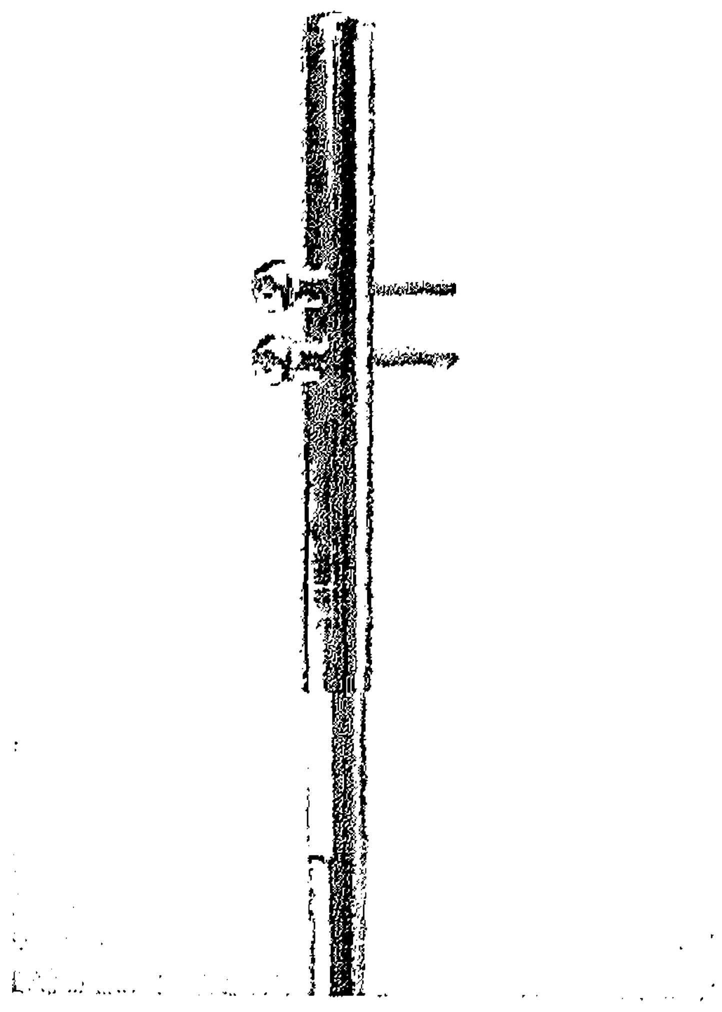

Figure 2-3. After interlocking the nail is rotational stable but remains dynamic.

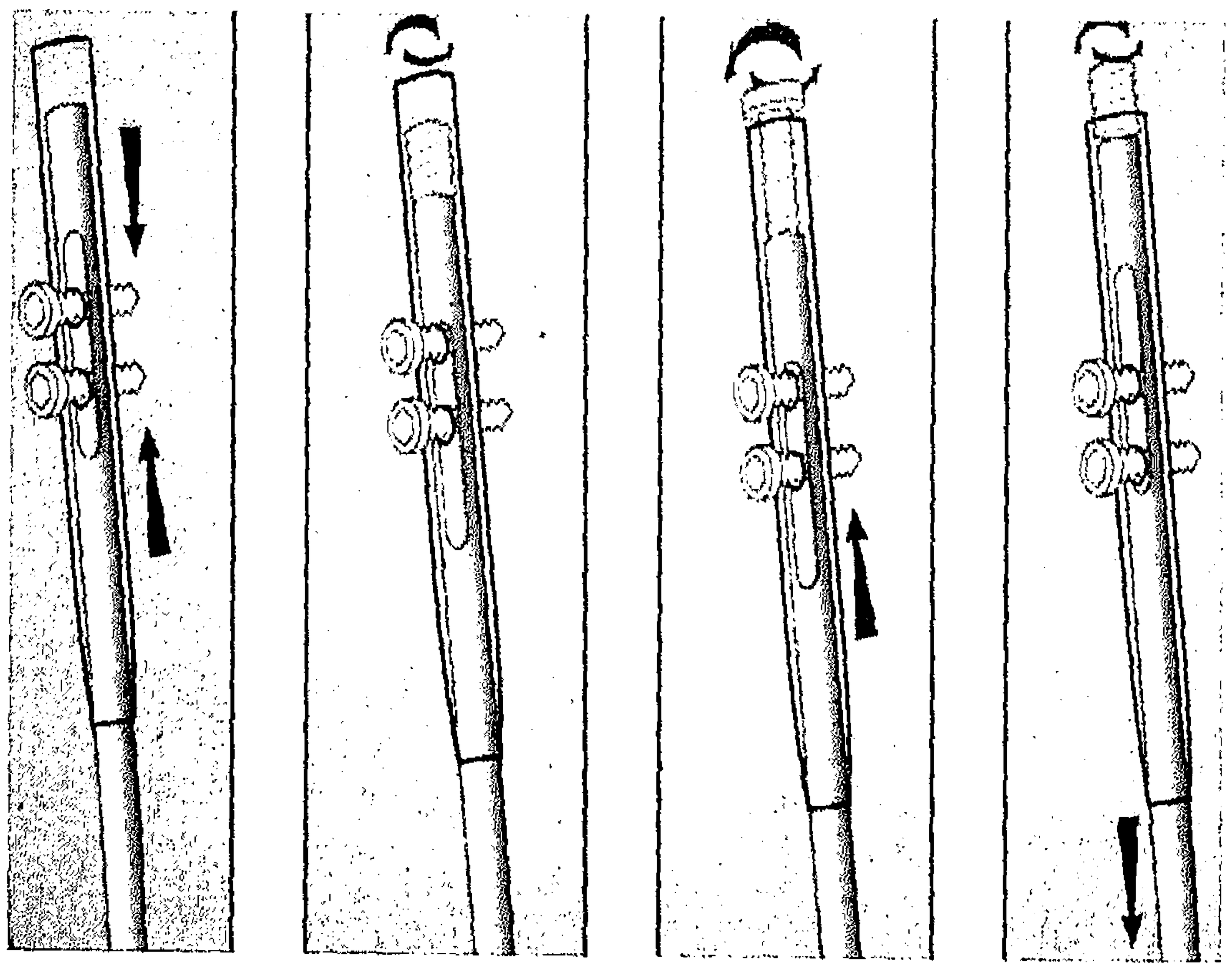

Figure 2-4. The different configurations of the TLN®: from left to right: dynamic, static, compression, distraction.

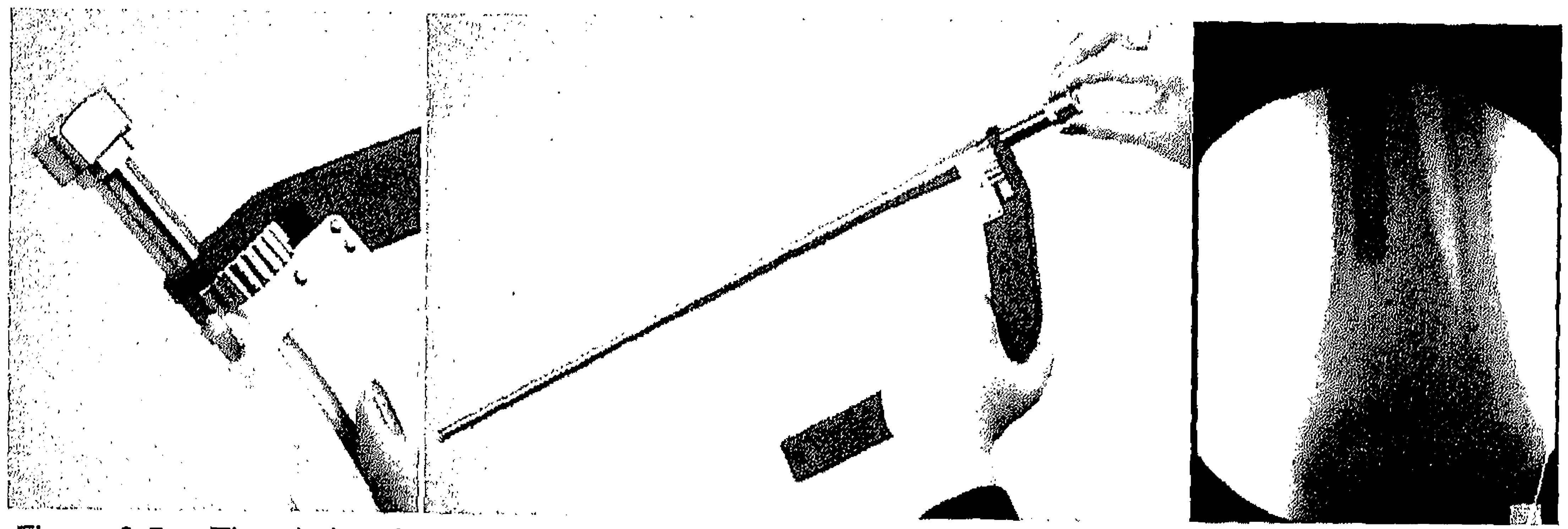

Figure 2-5a. The aiming device and nail before introduction (left and centre). Introduction of the nail (right).

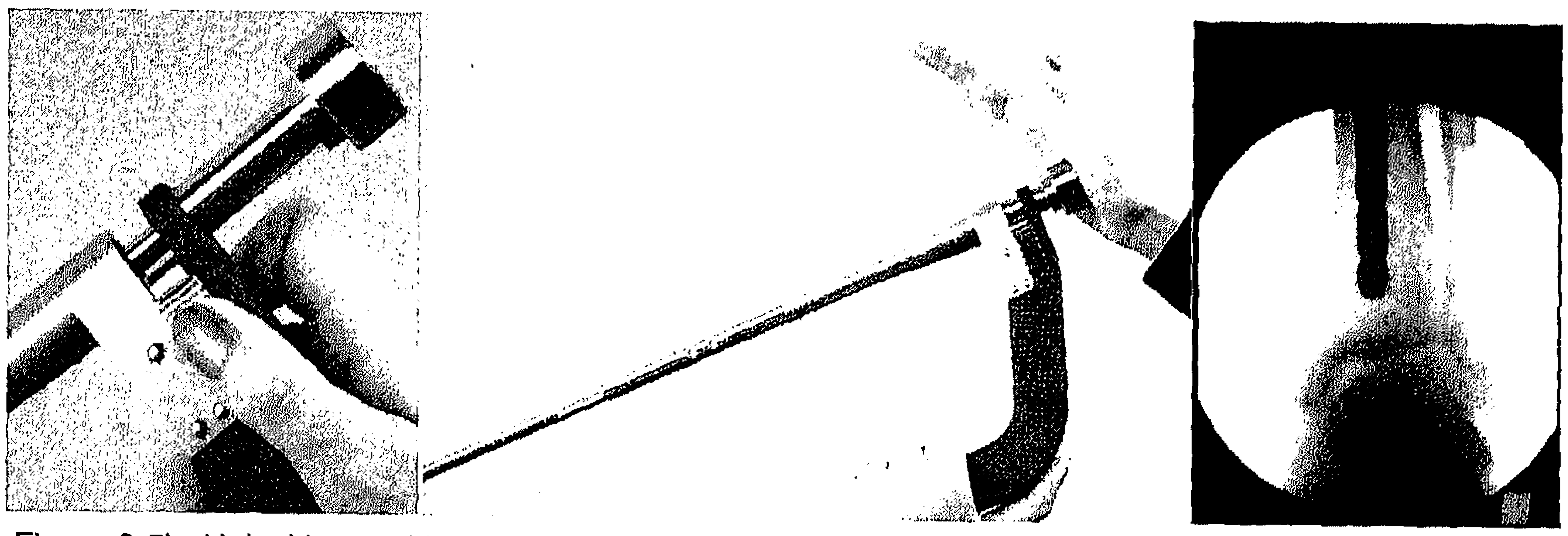

Figure 2-5b. Unlocking and lengthening of the nail (left and centre). After lengthening the nail tip lies in the metaphyseal region (right).

The Telescopic Locking Nail® for the humerus

For humeral fractures the first idea was to use the inner nail of the TLN® system. The straight 9 mm nail however was too rigid to be used in the humerus. Iatrogenic fractures with introduction and secondary breaking out of the nail were major complications (Figure 2-6). As the humerus is a bone with specific anatomy, loads and biomechanics it needs a specific nail instead of an implant derived from a tibial or femoral nail. A modified TLN®, without telescope, to be introduced with the same instruments and target device had to be developed. Because the specific for the TLN® designed screws with partial tread under the screw head did not have the same good purchase in the, often osteoporotic, bone of the humerus, these also needed replacement (Figure 2-7).

The Telescopic Locking Nail® for the humerus had to meet the following conditions:

1) Antegrade and retrograde introduction should be possible.
2) Sufficiently elastic.
3) Compression over the fracture to create extra-stability.
4) Strong 4.5 mm locking bolts.

Figure 2-6: The first prototype of the humeral TLN® breaking out.

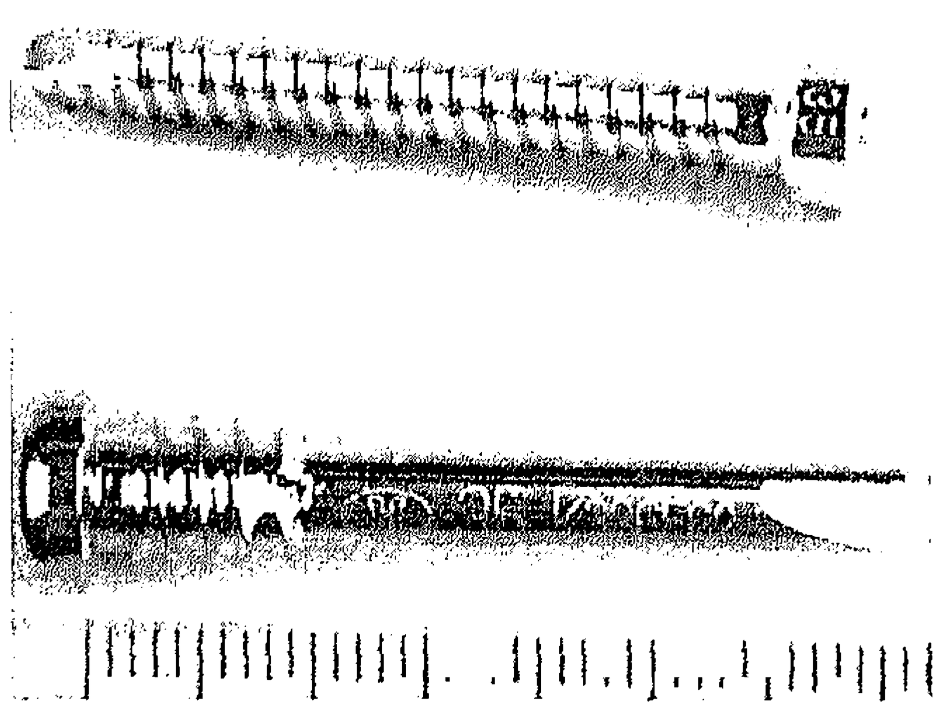

Figure 2-7: The locking screw for the humeral nail (above) and. the classic locking screw for the TLN (below)

The locking bolts of 4,5 mm improve stability through the higher nail-bone interference and stronger bone-bolt interface (Figure 2-7). This meant the nail had to be at least 9 mm at the locking hole section. To give the nail the necessary elasticity for save introduction and fracture healing the diameter of the central part was reduced to 7.6 mm. This was the second prototype (Figure 2-8). The humerus does not need a slot of 2.5 cm for dynamisation and this was replaced with an oblong locking hole of 1 cm. The third prototype became the definite nail for the humerus.

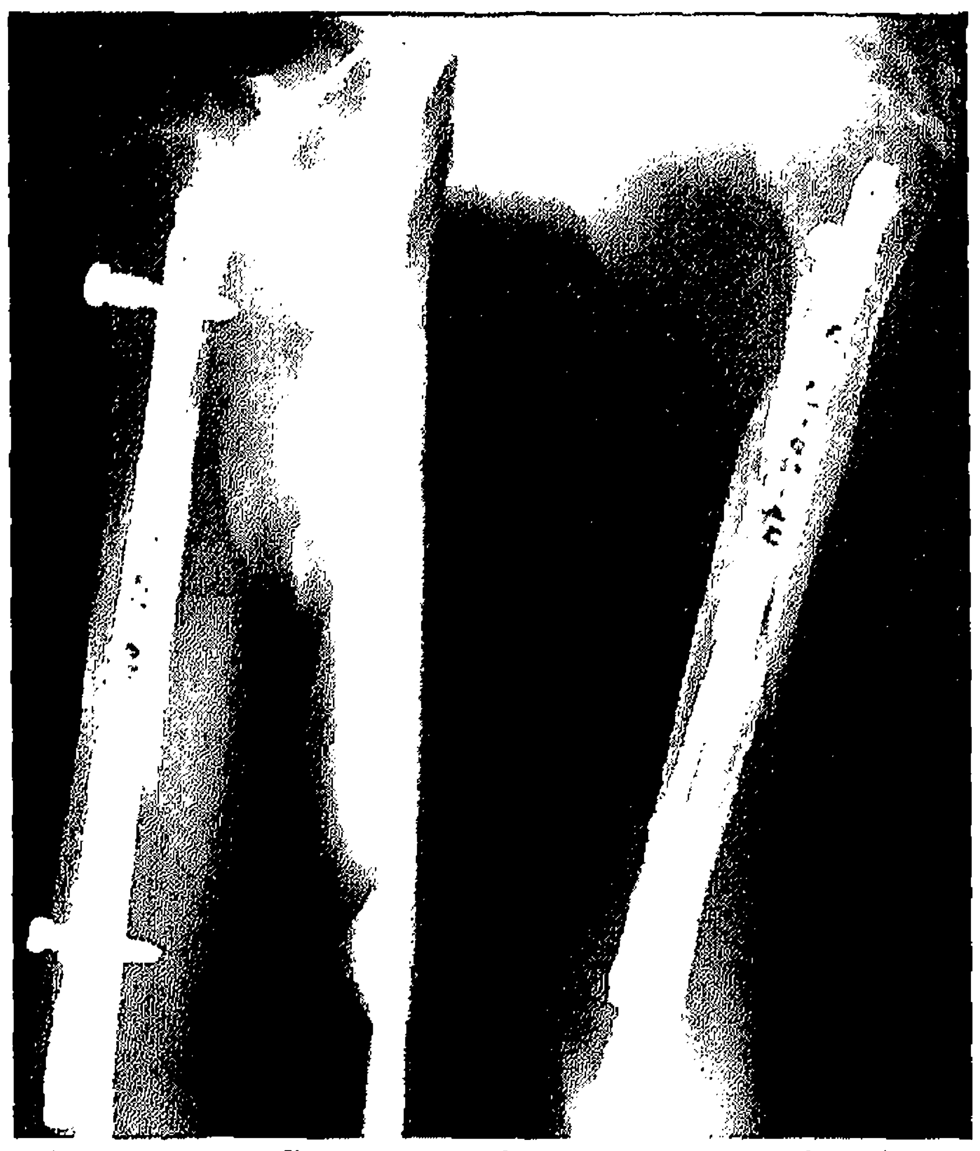
Figure 2-8: The second prototype of the TLN® humerus with a smaller middle section but still with a slot in the proxiomal end.


Figure 2-9: The definitive version of the TLN Humerus with an oblong locking hole at the proximal end.

Distal interlocking is possible through three locking holes, two holes are oriented in the same plane as the proximal oblong hole and one at a right angle with it. The oblong locking hole makes dynamic and static interlocking possible (Figure 2-9). In the case of transverse and short oblique fracture and non-unions compression can be applied with a compression screw. This screw has to be introduced at the proximal end and works as an axial setscrew by taking support on the locking bolt.

After distal interlocking, tightening the compression screw makes the nail back out again and compresses the fracture (Figure 2-10).

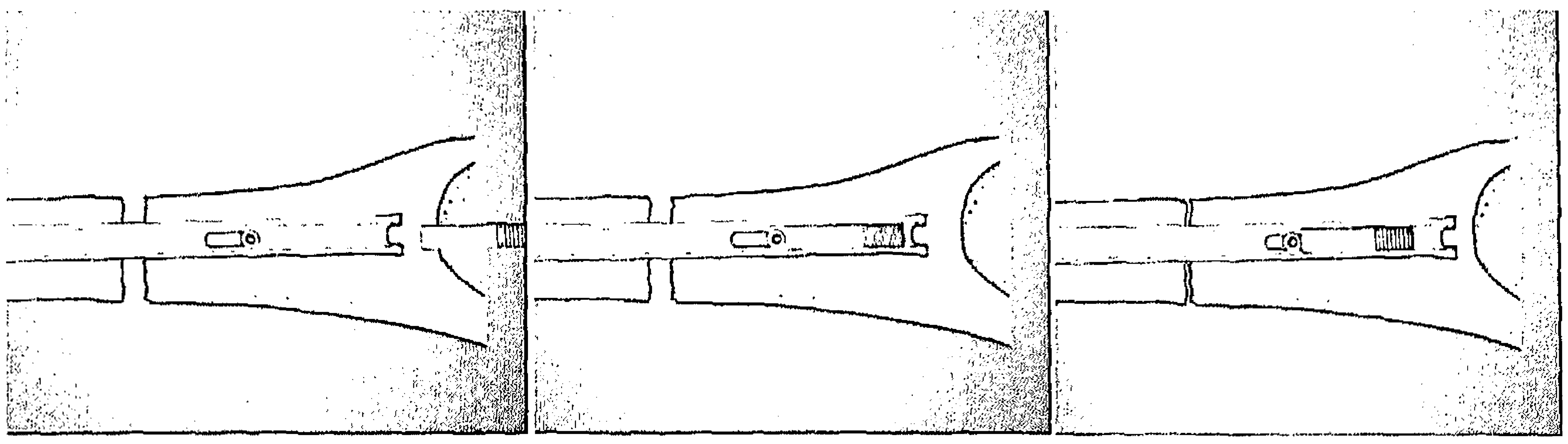
Figure 2-10. The compression system of the TLN® humerus: left: introduction of the compression screw; centre: the screw engages the locking screw, and right: by tightening the compression screw, the fracture is compressed.

The nail can be introduced both antegrade and retrograde. Because of the broader ends there is a risk that due to bone ingrowth nail removal is problematic. To prevent this the distal end is provided with cutting edges to facilitate nail removal (Figure 2-11).

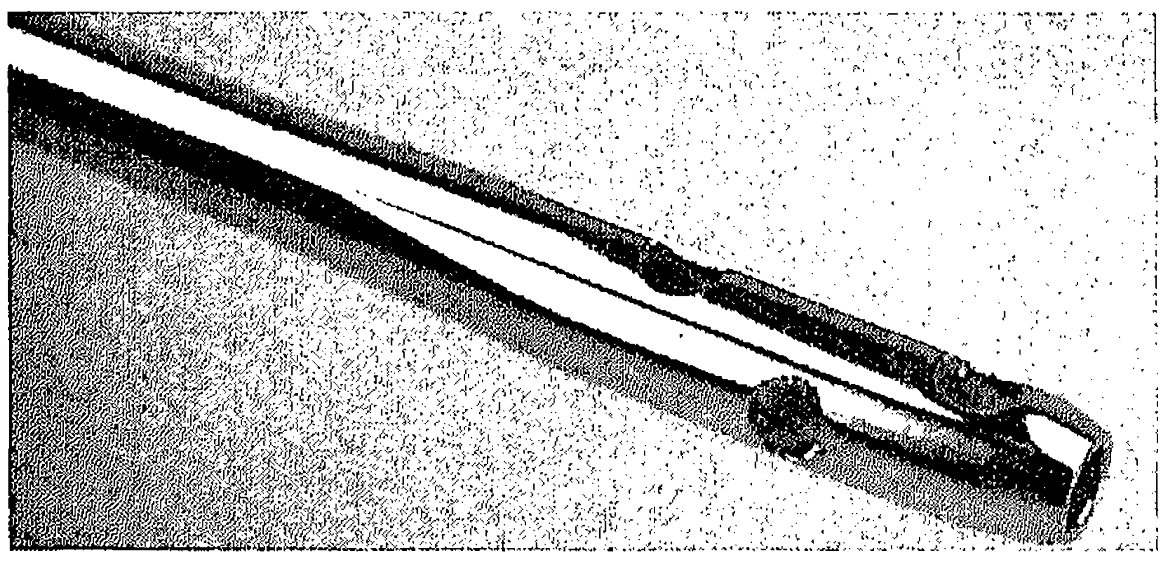

Figure 2-11: The distal end of the TLN® with the cutting edges to facilitate nail removal.

After the first clinical results in a pilot study had been successful the start for a larger multicentre feasibility study was given. Nine hospitals in the Netherlands took part in it. The results of this study are discussed in this thesis.

CHAPTER III

Technique of Humeral Nailing

In nailing of humeral fractures both antegrade and retrograde introduction of nails are possible. Both ways of introduction have their own ad- and disadvantages. Which technique is used mainly depends on the implant and the personal preference and skills of the surgeon. The fracture pattern, fracture level and last but not least the patient should be taken into account.

Anatomy of the humerus

The medullary canal of the humerus differs from that of tibia or femur. Tibia and femur have an isthmus, widening proximally and distally into the metaphysis. This typical form made the technique of medullary impingement for femoral and tibial nails possible. The humeral medullary canal has a more trumpet like form, wide and circular proximal and narrower in the distal part with a more flattened medullary canal in the antero-posterior direction, without a typical isthmus. Furthermore there is an anterior angulation of about 30° of the condyles (Figure 3-1). It made nailing of humeral fractures more difficult because the nails could not be impinged without extensive reaming. The smaller distal part can lead to jamming of the nail in the medullary canal, which may cause distraction of the fracture or iatrogenic fractures at the distal humeral shaft if the nail is introduced further. With retrograde introduction the risk for iatrogenic fractures is very high due to the narrower canal and the harder cortex.

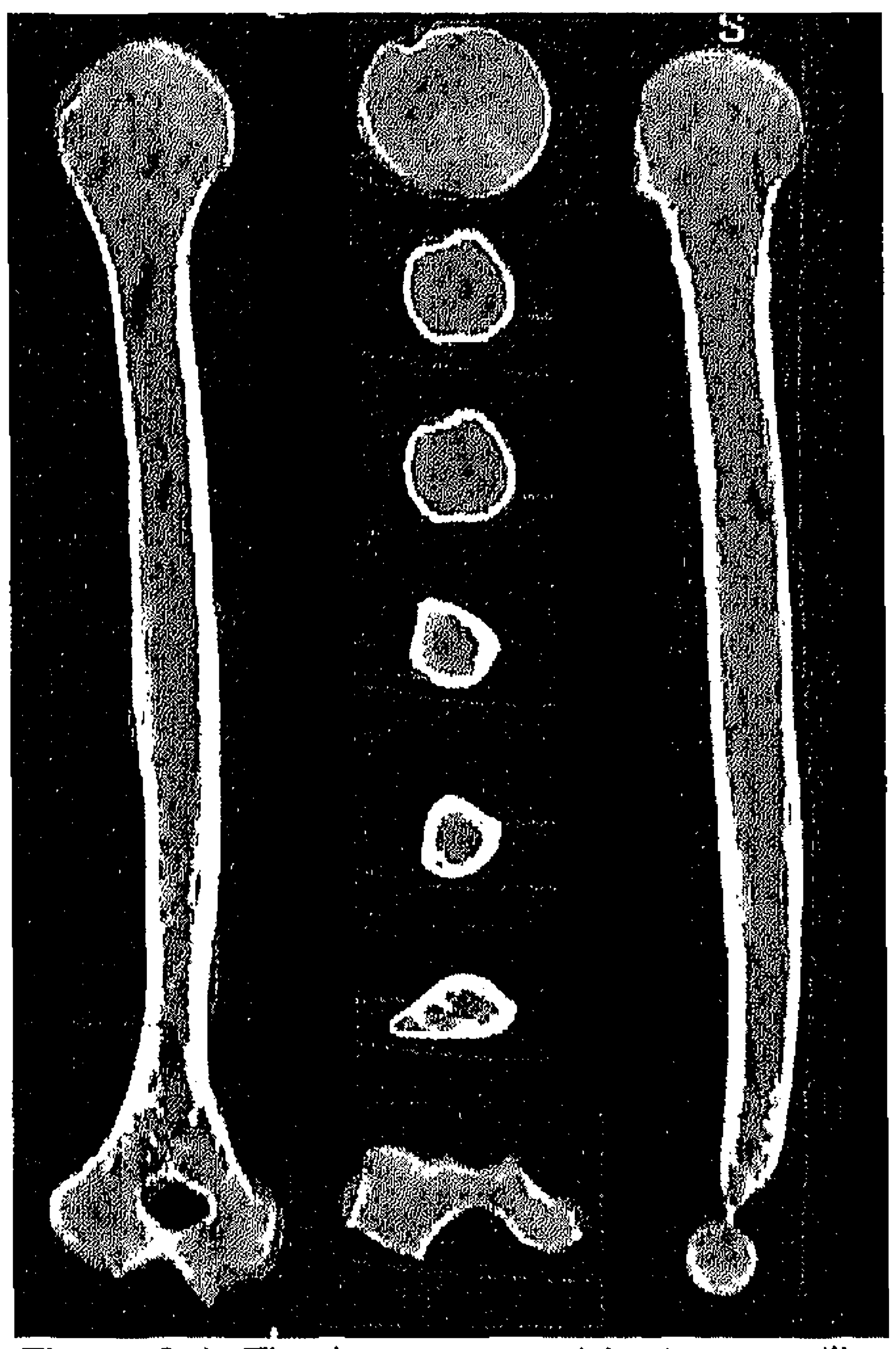

Figure 3-1: The humerus and its trumpet-like form of the medullary canal

The development of interlocking nails for the humerus allowed thinner nails not depending on nail-bone interference for stability, abolishing extensive reaming.

Antegrade Nailing

As always the success of the operation depends on the preparation. Before starting with introducing a humeral nail the patient should be positioned properly and it should be checked whether the complete upper arm projects free when using fluoroscopy. With antegrade nailing the patient is placed in the supine position with the affected arm positioned over the table edge supported by an armrest (Figure 3-2a). An alternative position is the beach-chair position with the upper part of the body elevated for about 30°. Careful desinfection and draping is done, taking care that the arm can be moved freely in anteversion and abduction. A stab or very small incision is made at the anterolateral side of the shoulder joint just anterior to the acromion. The muscle fibres of the deltoid are split in the longitudinal direction. The rotator cuff is opened with a stab incision. Other authors recommend opening the rotator cuff under sight and closing it securely after nail introduction. Under X-ray control the medullary canal is opened just medial to the greater tubercle with an awl (Figure 3-2b).

While the fracture is reduced manually the guide wire with knob is introduced and passed over the fracture (Figure 3-2c). The shaft now can be reamed. Minimal reaming is 10 mm (Figure 3-2d and e). After measuring the nail length, the nail is mounted on the

Figure 3-2a. Correct positioning of the patient in supine position and X-ray control.

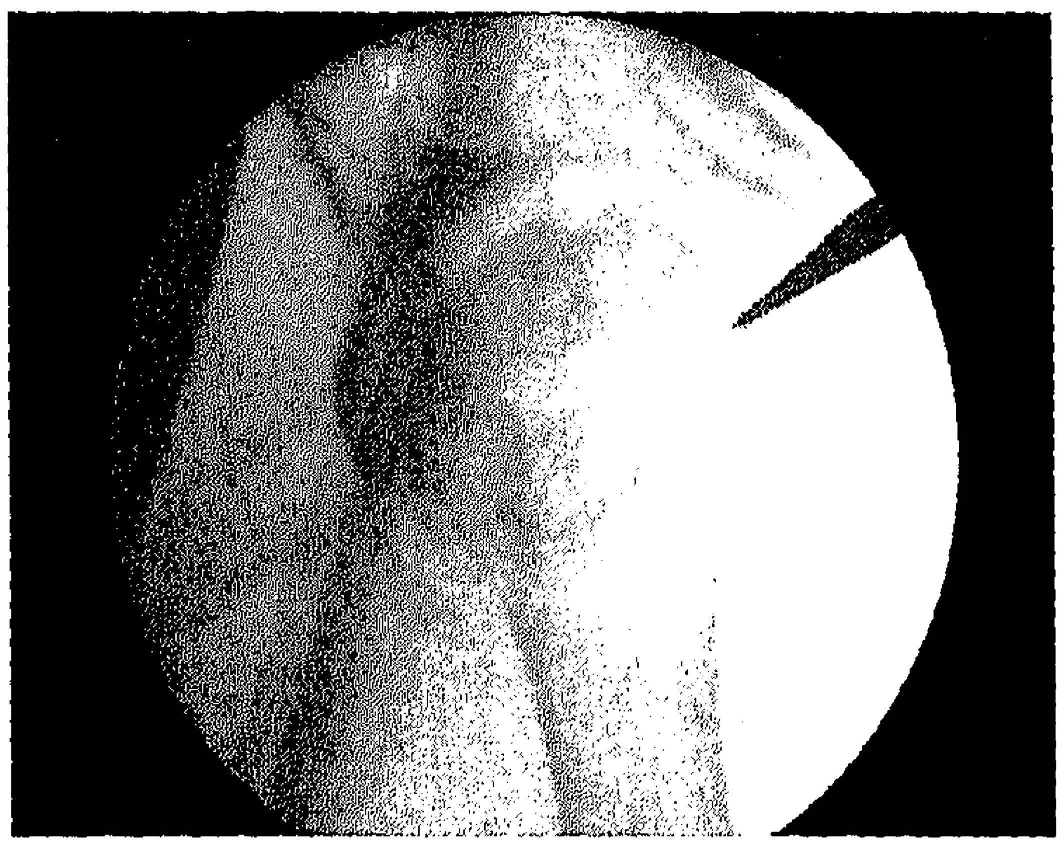

Figure 3-2b. Opening of the medullar canal medial from the greater tubercle.

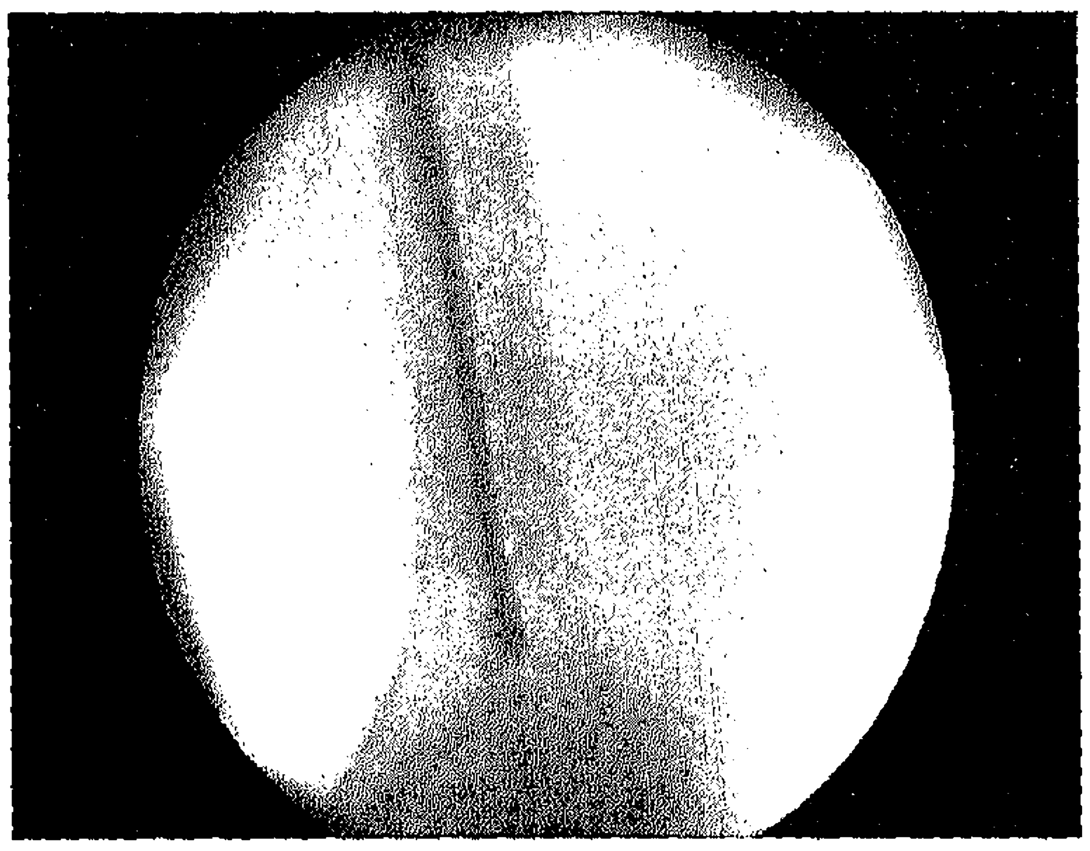

Figure 3-2c. Introduction of the guide wire and reposition of the fracture.

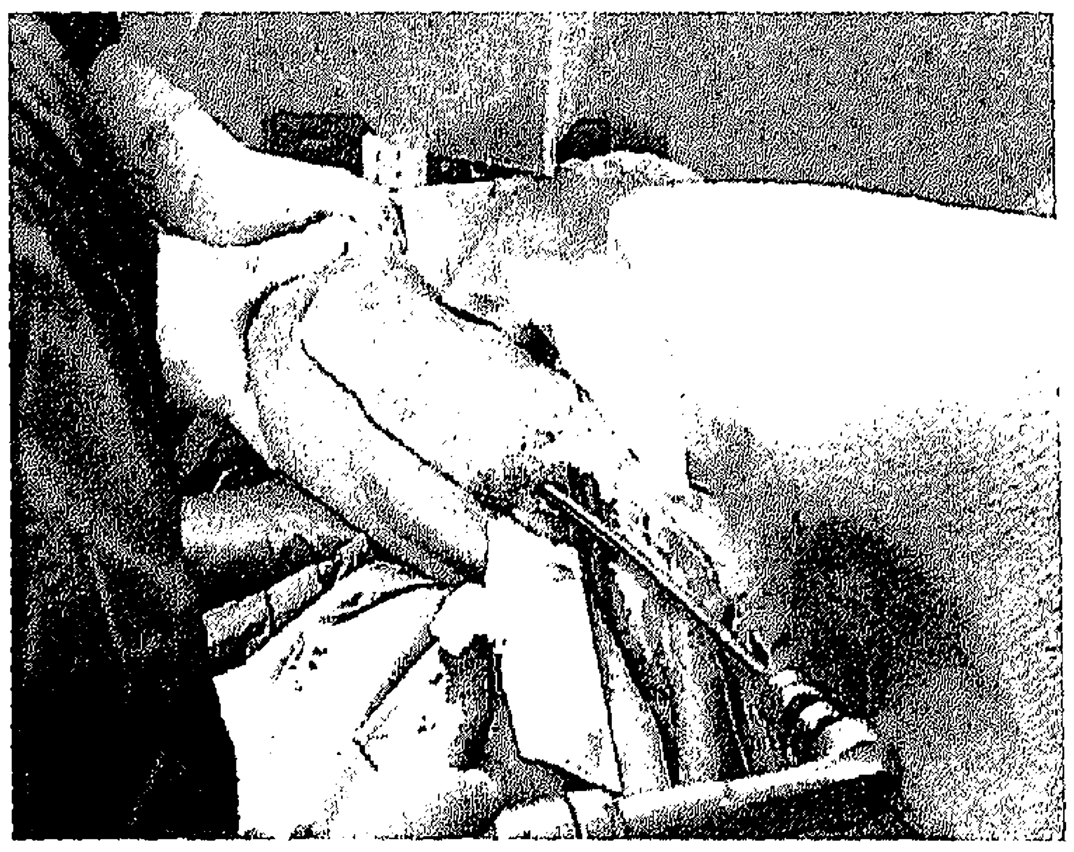

Figure 3-2d. Reaming of the medullar canal

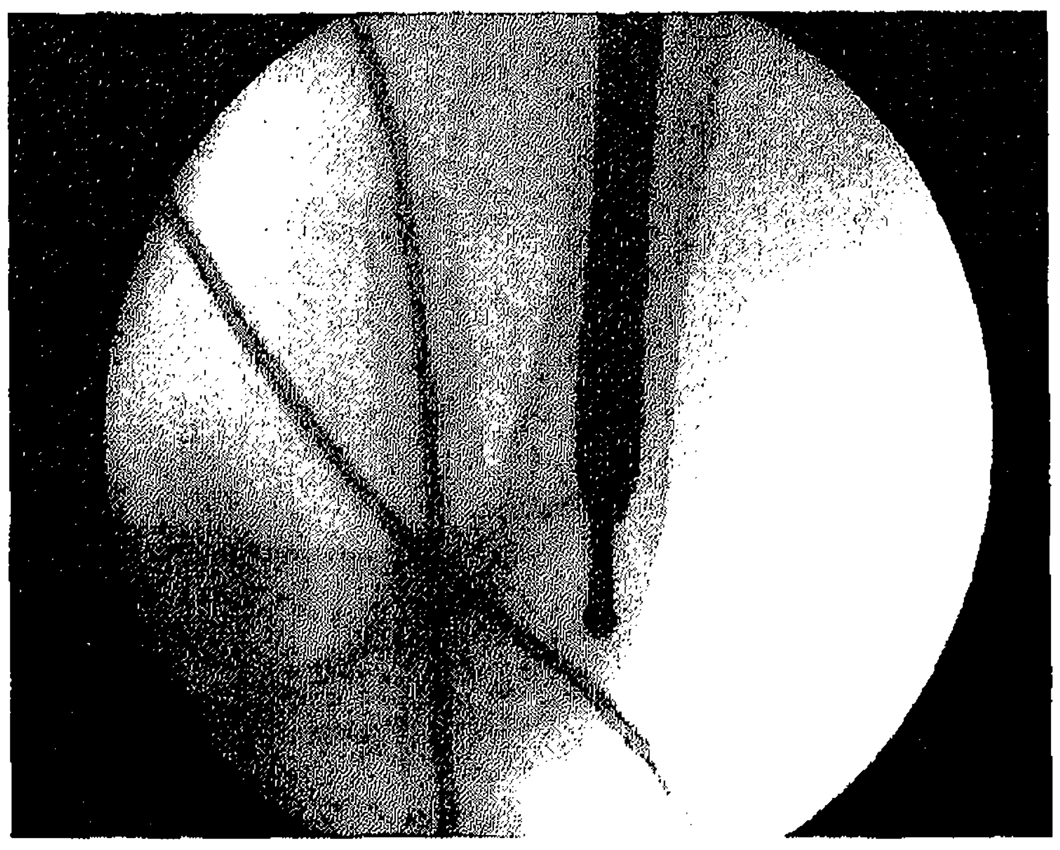

Figure 3-2e. Reaming of the intramedullar canal

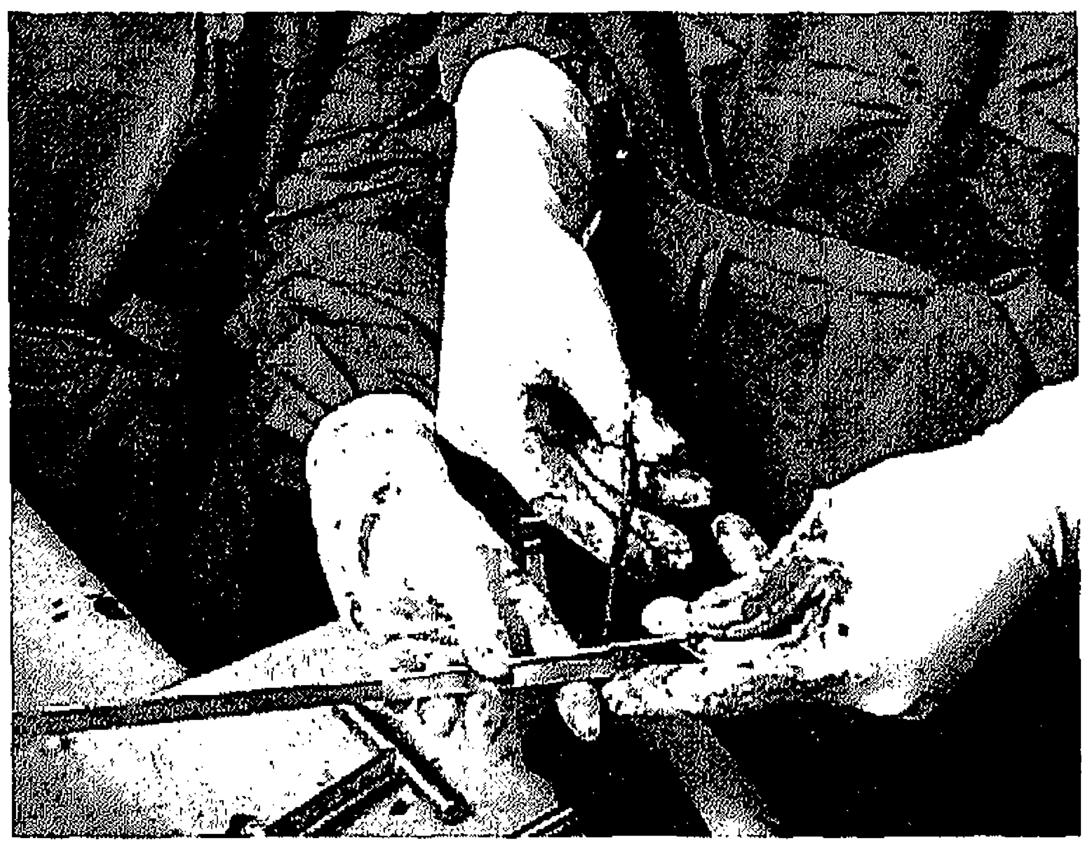

Figure 3-2f. Determining the nail length

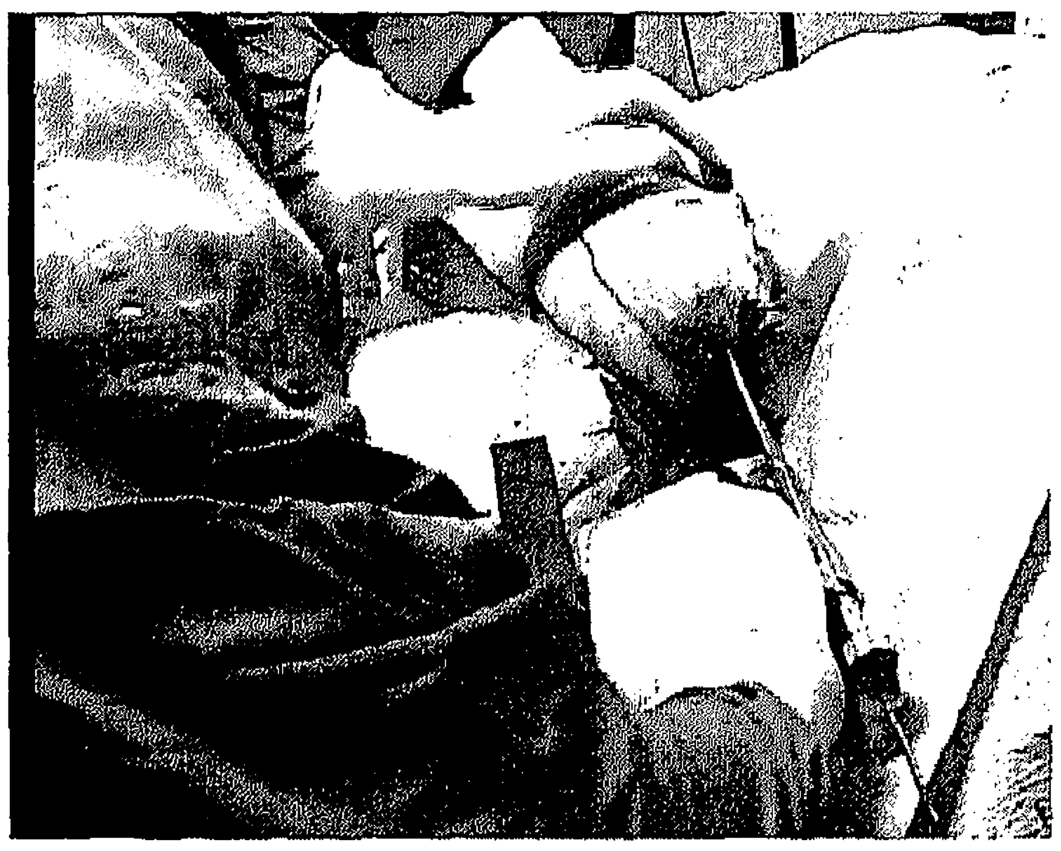

Figure 3-2g. Introduction of the nail

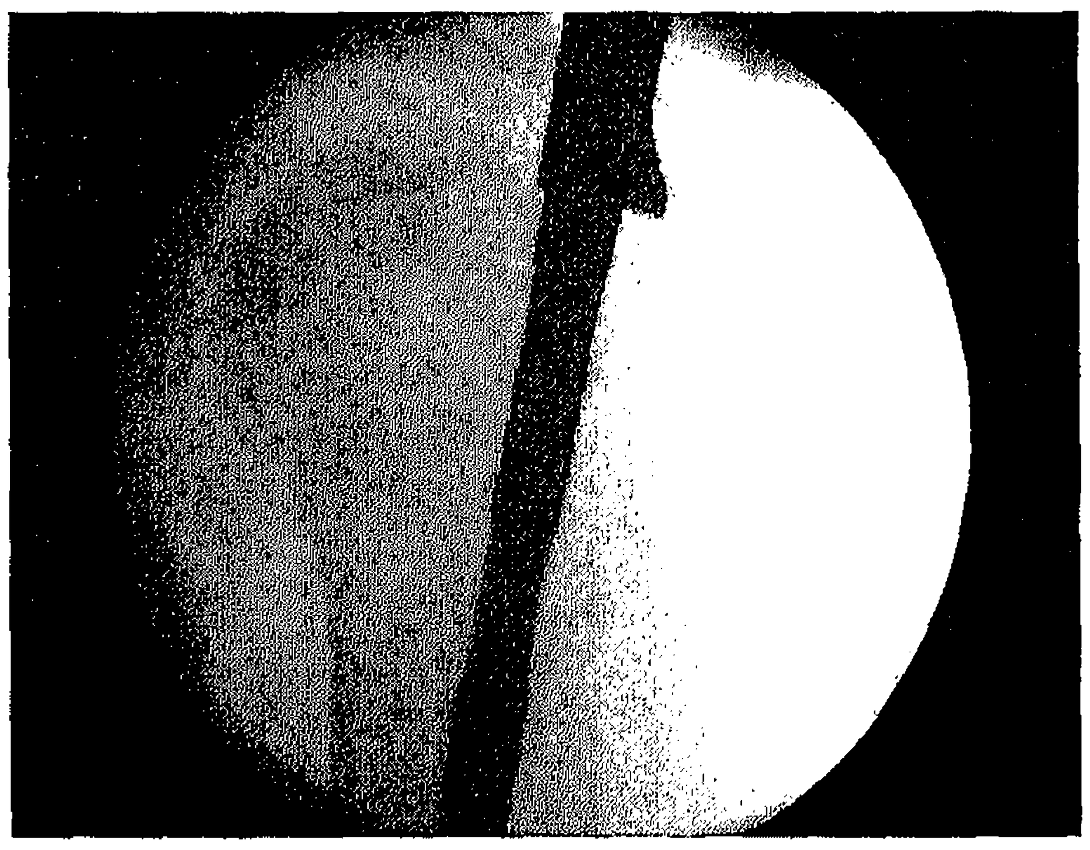

Figure 3-2h. Control of correct positioning of the nail

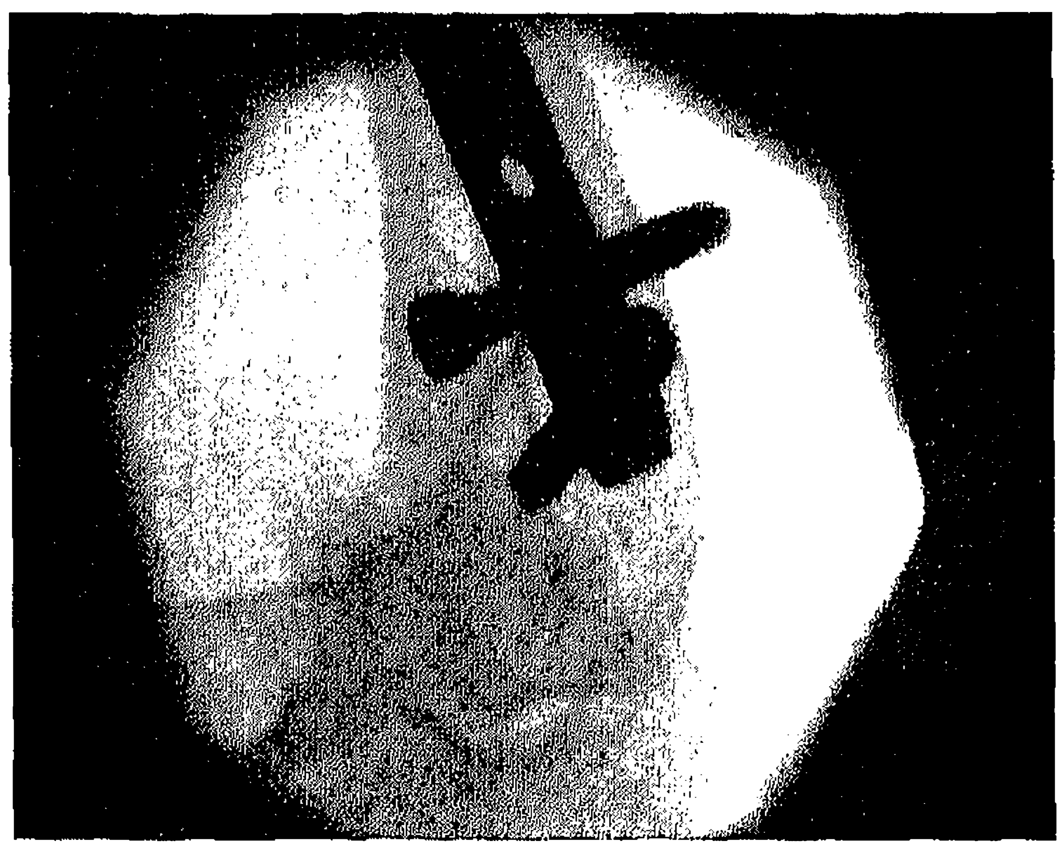

Figure 3-2i. Distal interlocking

ntroduction ev ce and t e gu e w re s replaced by a wire without knob. Then the nail is introduced (Figure 3-2f and g). Gentle rotating manoeuvres may be of help. It is very important to verify the depth of the nail with the image intensifier in different directions after introduction. It should at least be flush or slightly deeper then the contour of the humeral head to avoid subacromial impingement. In the case of the TLN® a special mark on the target device indicates the correct position of the nail (Figure 3-2h).

After removal of the guide wire, the nail can be locked with the locking bolts. At the proximal side this is done through the aiming device in the latero-medial direction. Dynamic or static locking is possible. Distally a free hand technique is used. Distal locking should be performed after surgical exposure of the distal humerus to avoid damage to neurovascular structures. The preferred direction is antero-posterior. Latero-medial direction is also possible but carries more risk for damage to the radial nerve. It should only be used on indication and without exception under direct sight (Figure 3-2i).

After interlocking distally, depending on the fracture type compression can be given with the axial set screw. In doing this the nail backs out and depending on its original depth, it may protrude into the shoulder joint. To prevent this, one should lock first through the "static" locking hole after the nail has been introduced "flush" with the surface of the humeral head. The aiming device is unlocked and the nail is introduced further till the locking screw is in the "dynamic" position. When after distal interlocking, compression is given, the nail never can back out further than its original depth, under the surface of the humeral head (Figure 3-3a-f).

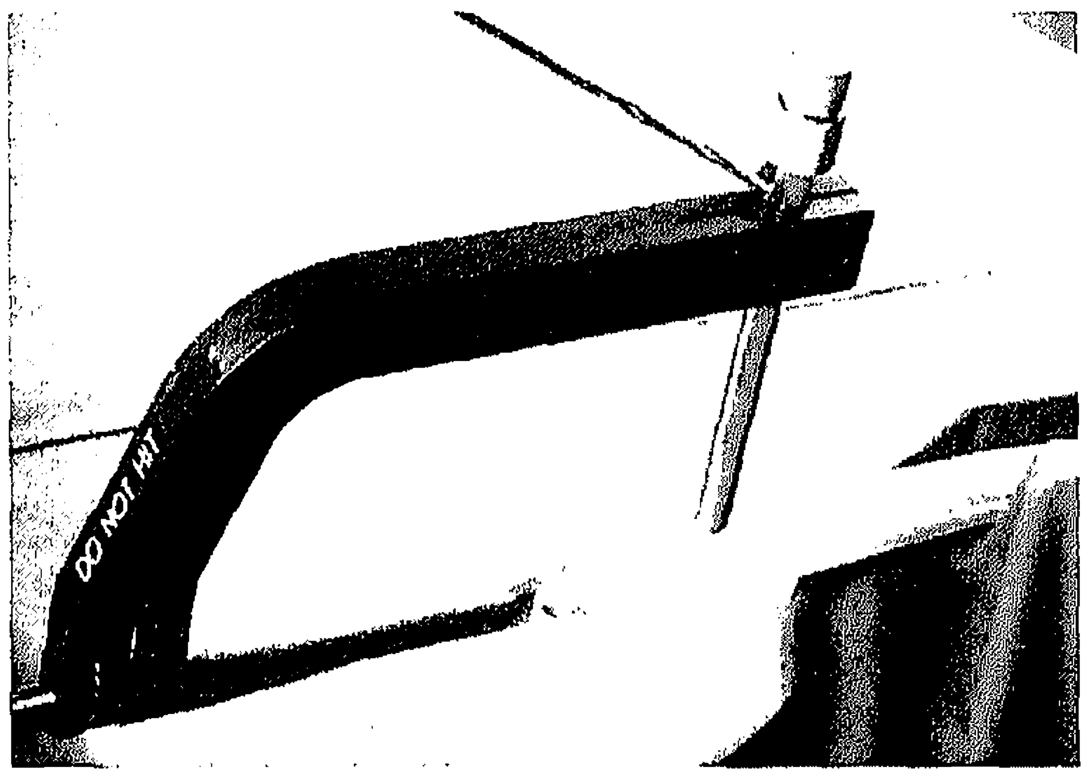

Figure 3-3a: Proximal interlocking in the "static"position.

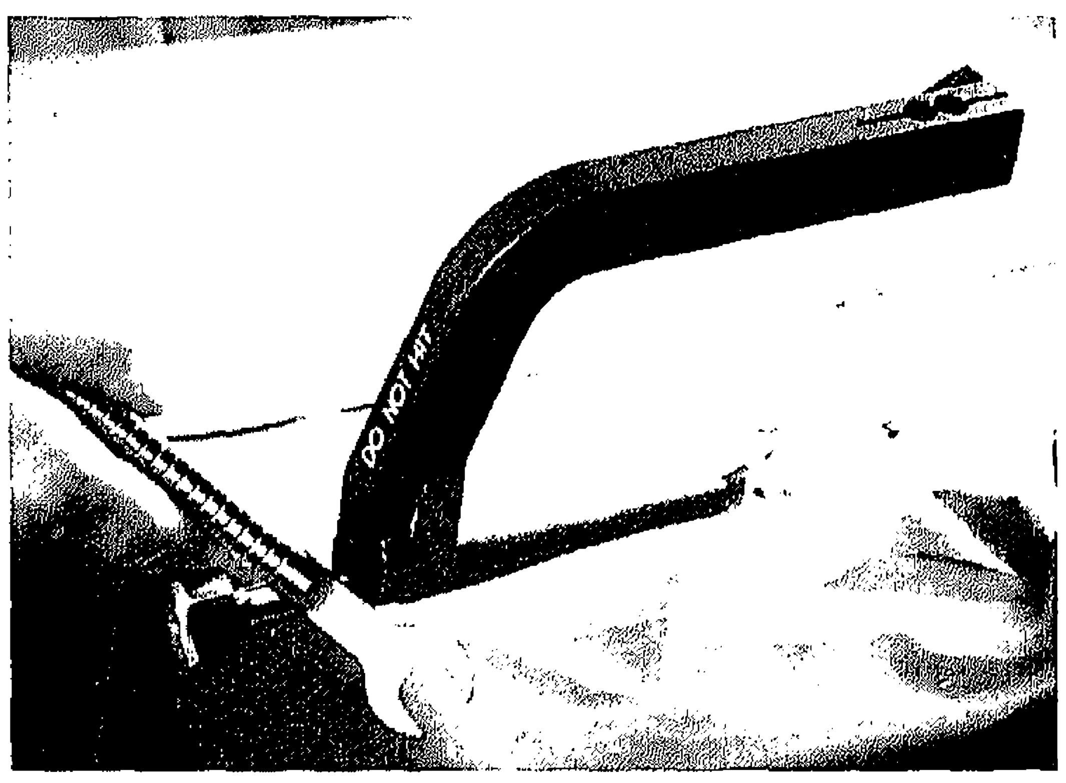

Figure 3-3b: Loosening of the nut of the aiming device.

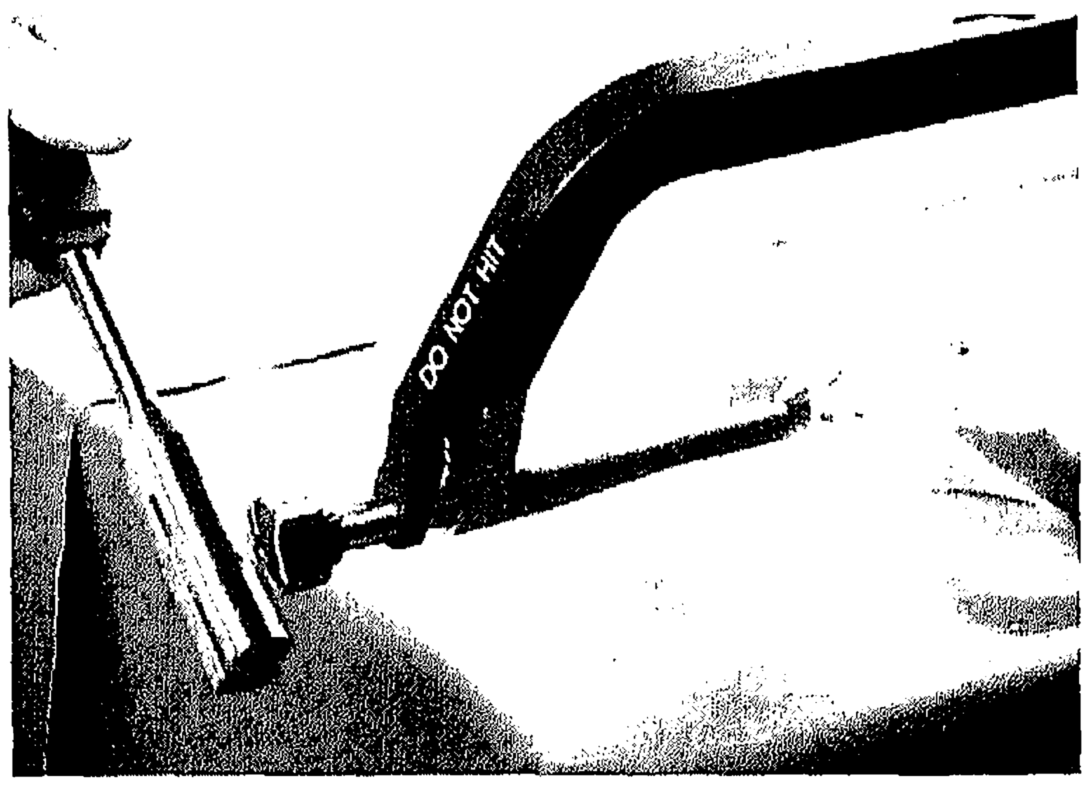

Figure 3-3c: The nail is driven further till the locking screw is in the "dymamic" position.

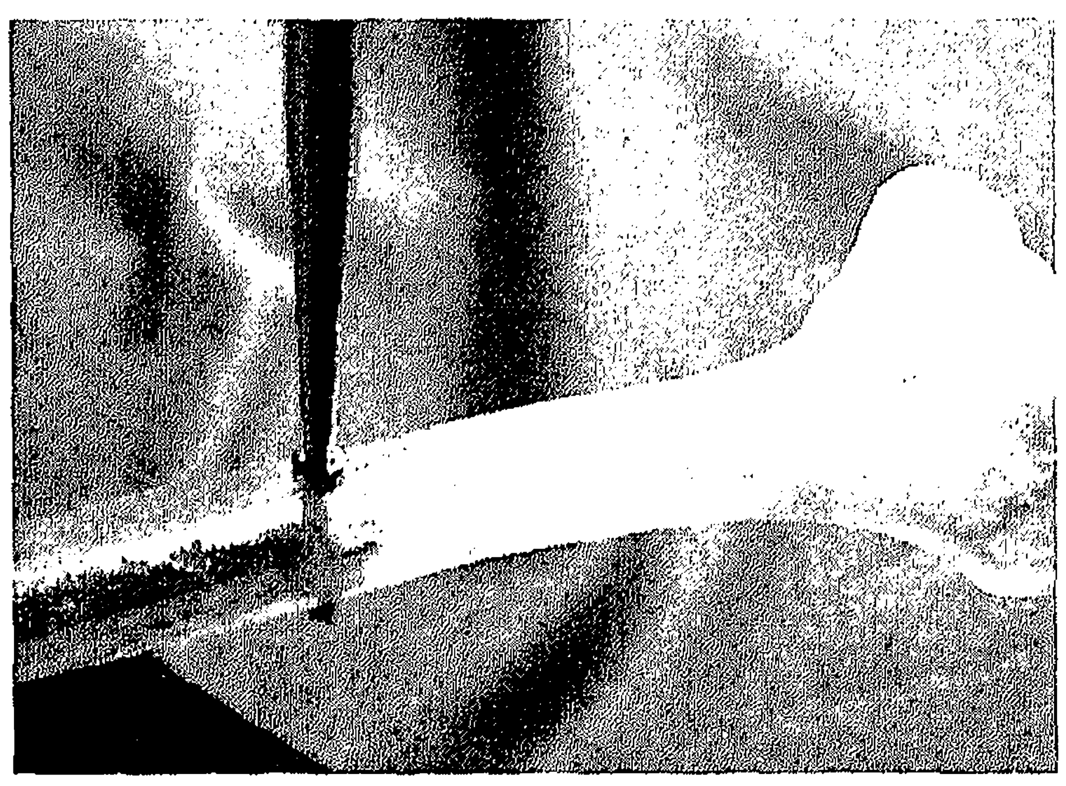
Figure 3-3d: Distal interlocking in the free-hand technique.

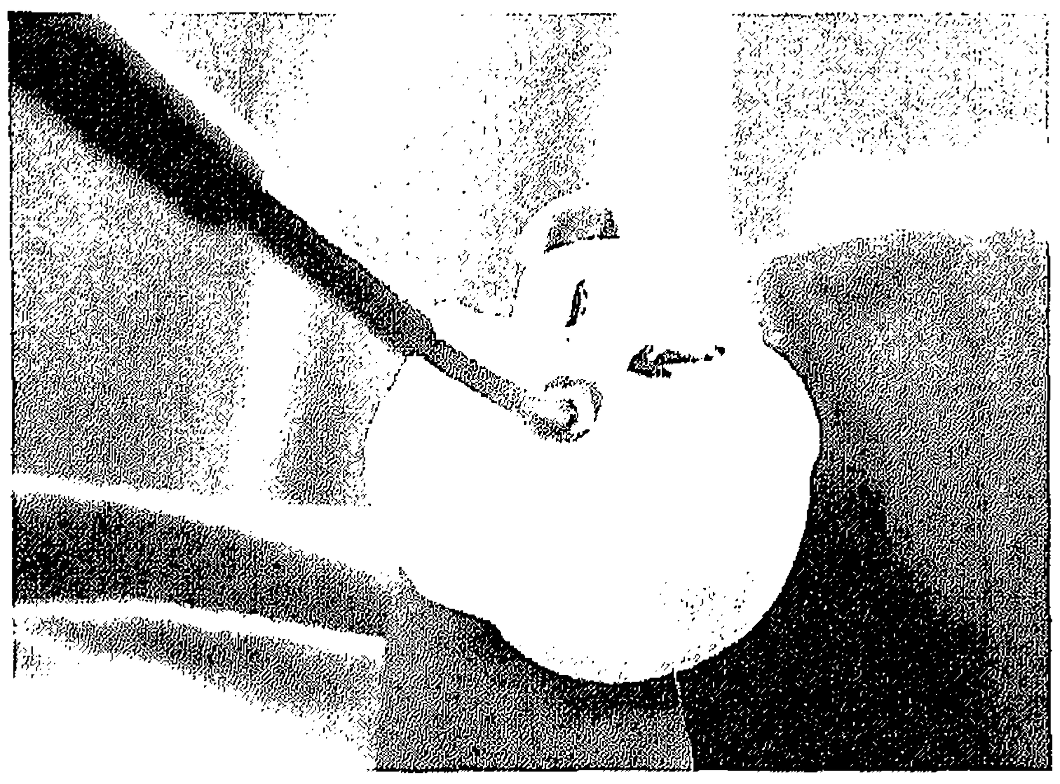

Figure 3-3e: The compression screw is introduced and tightened.

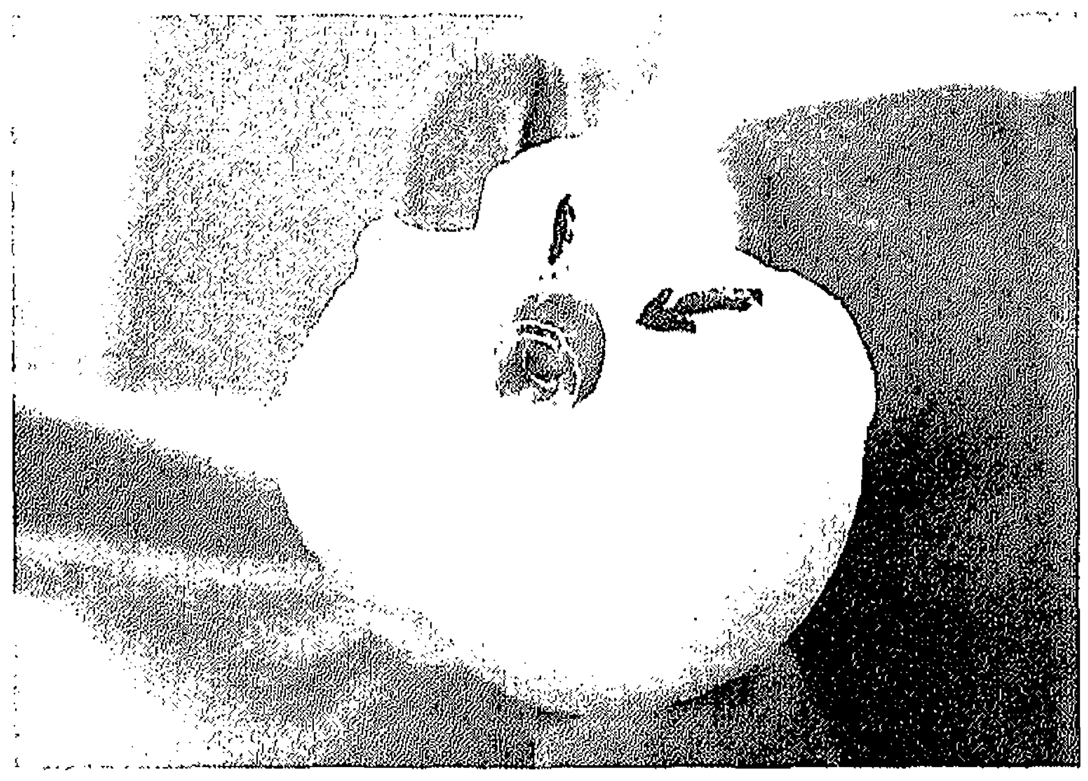

Figure 3-3f: The nail can not back out further than its original position.

Retrograde nailing

Retrograde introduction is often preferred in intramedullary nailing of the humerus because it is an extra-articular procedure. The patient is positioned in the prone position with the affected arm abducted 90° and pending on an armrest with the elbow flexed 90°. With the image intensifier it is verified that the complete humeral head can be visualized (Figure 3-4a). An incision is made over the distal humerus as far as the tip of the olecranon. The triceps muscle is split and the distal part of the humerus with the olecranon fossa is exposed (Figure 3-4b). There are two possibilities to open the medullary canal: the supracondylar or the fossa olecranon access. We prefer the fossa olecranon access because it is more in line with the intramedullary canal. The medullary canal is opened with a drill and the hole then is widened by subsequently using larger drills. Drilling is started at about 30° and when the drill has engaged itself in the cortex the drill is brought into the axis of the medullar canal (Figure 3-4c).

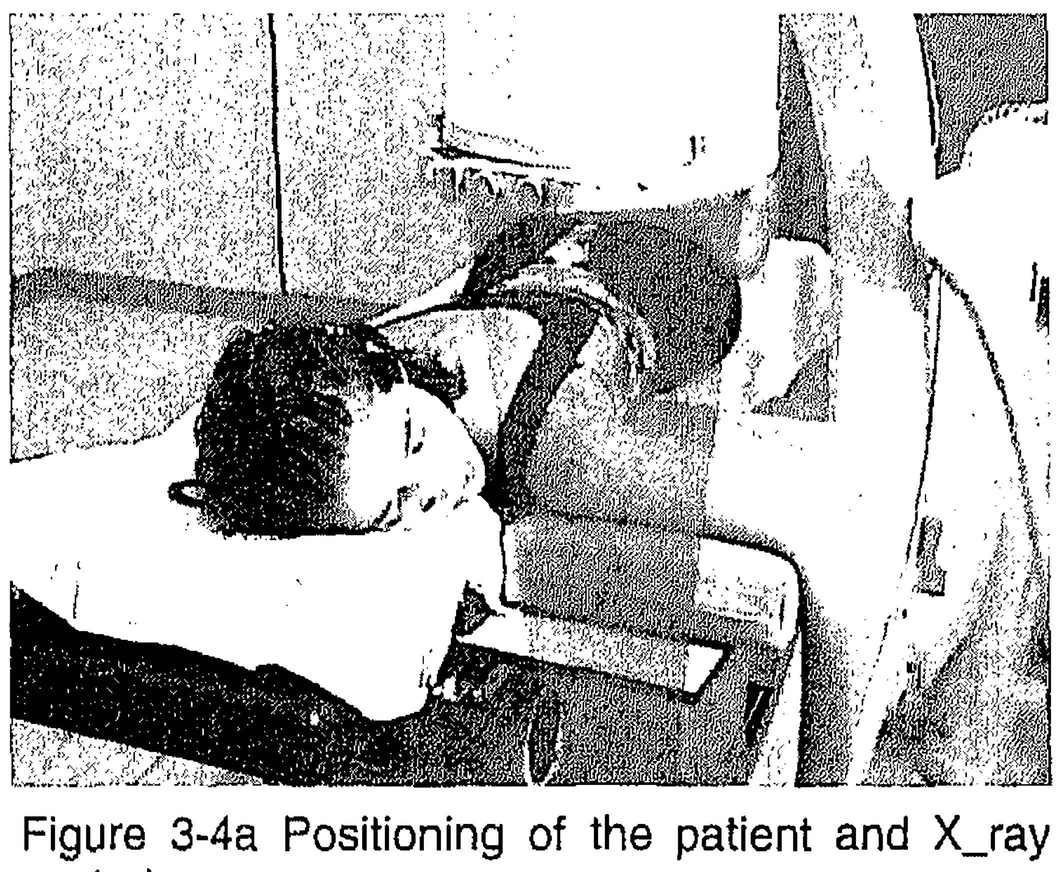

Figure 3-4a Positioning of the patient and X_ray control.

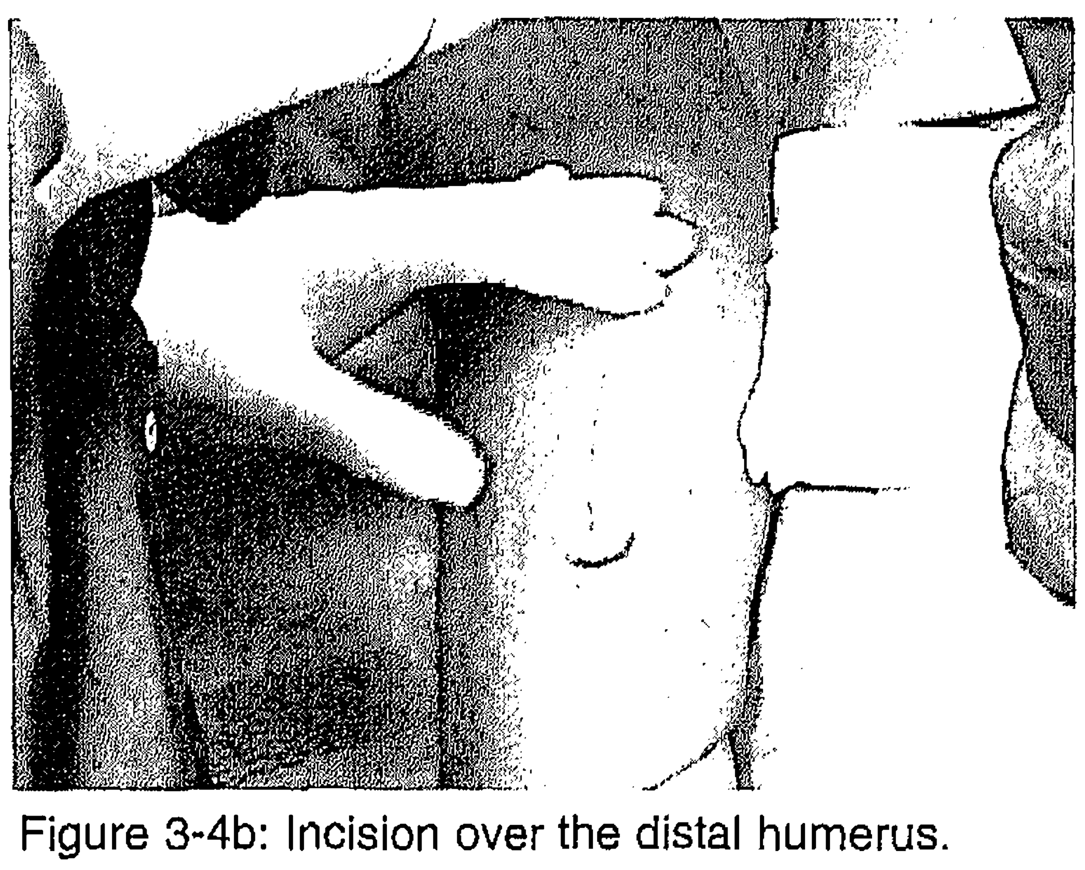

Figure 3-4b: Incision over the distal humerus.

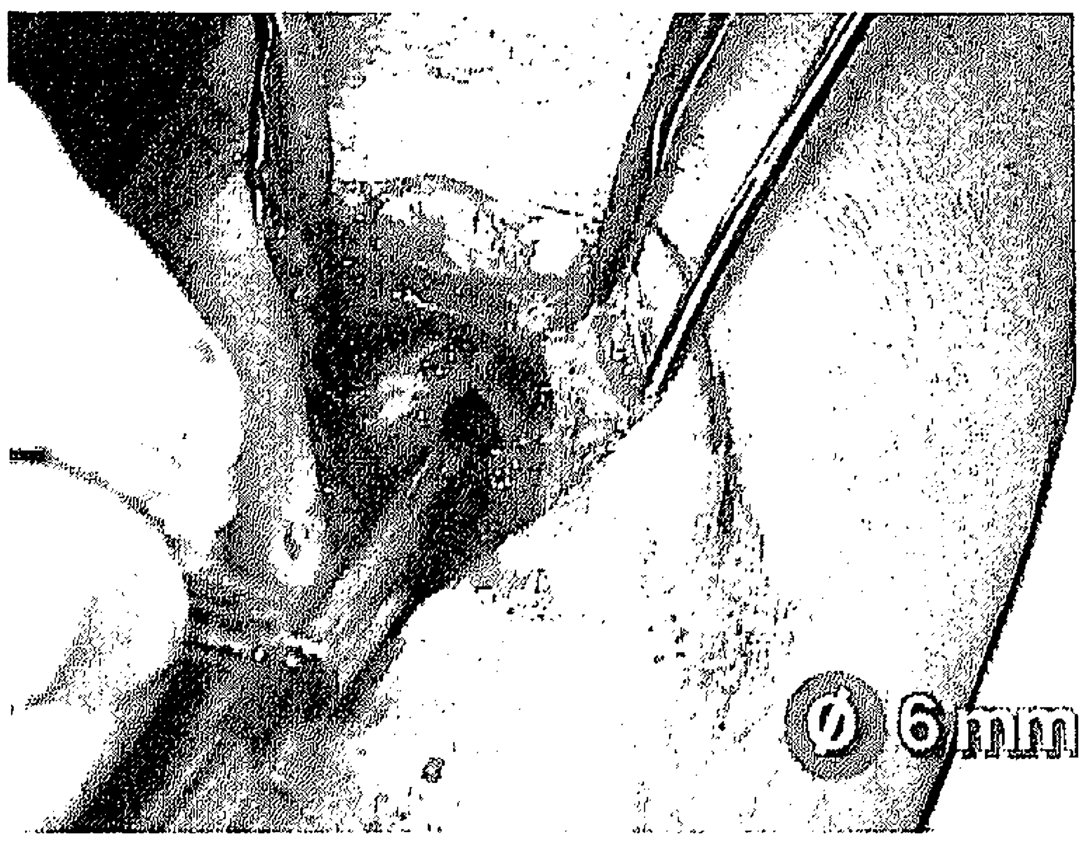

Figure 3-4c: Opening of the medullary canal proximal from the olecranon fossa.

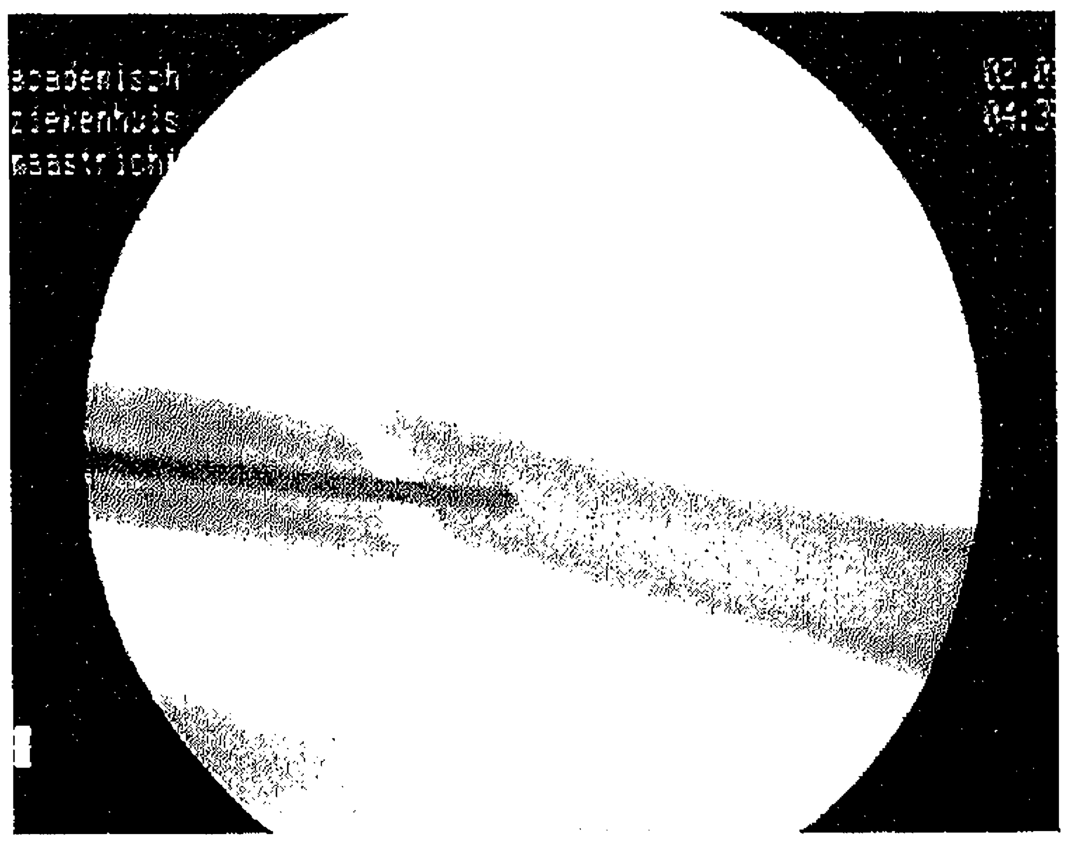

Figure 3-4d: Introduction of the guide wire.

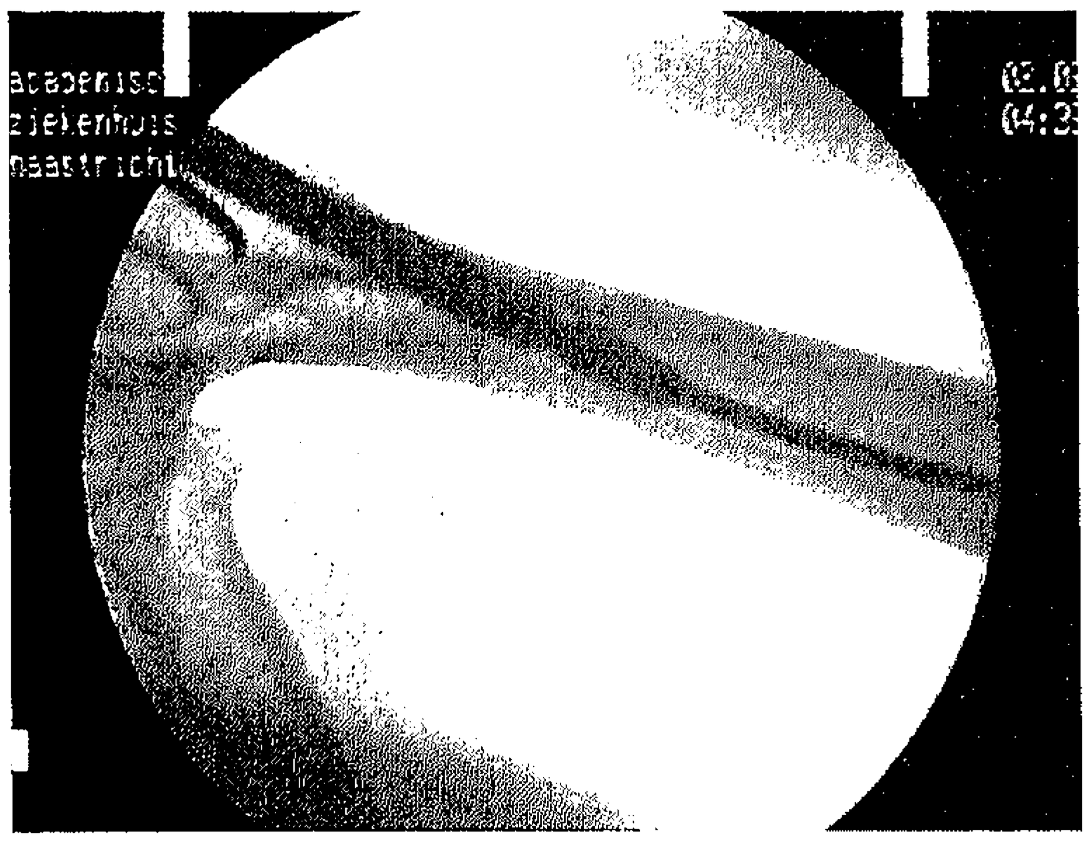

Figure 3-4e: Reaming of the medullar canal.

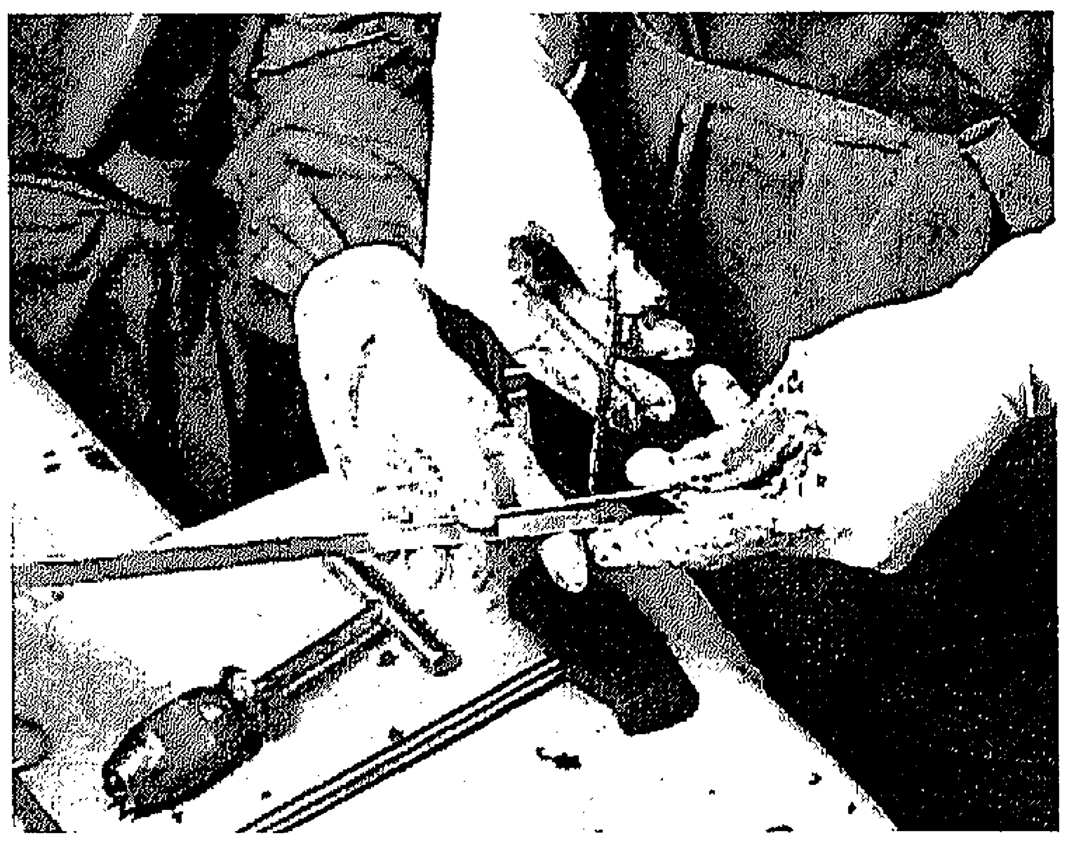

Figure 3-4f: Measuring correct nail length.

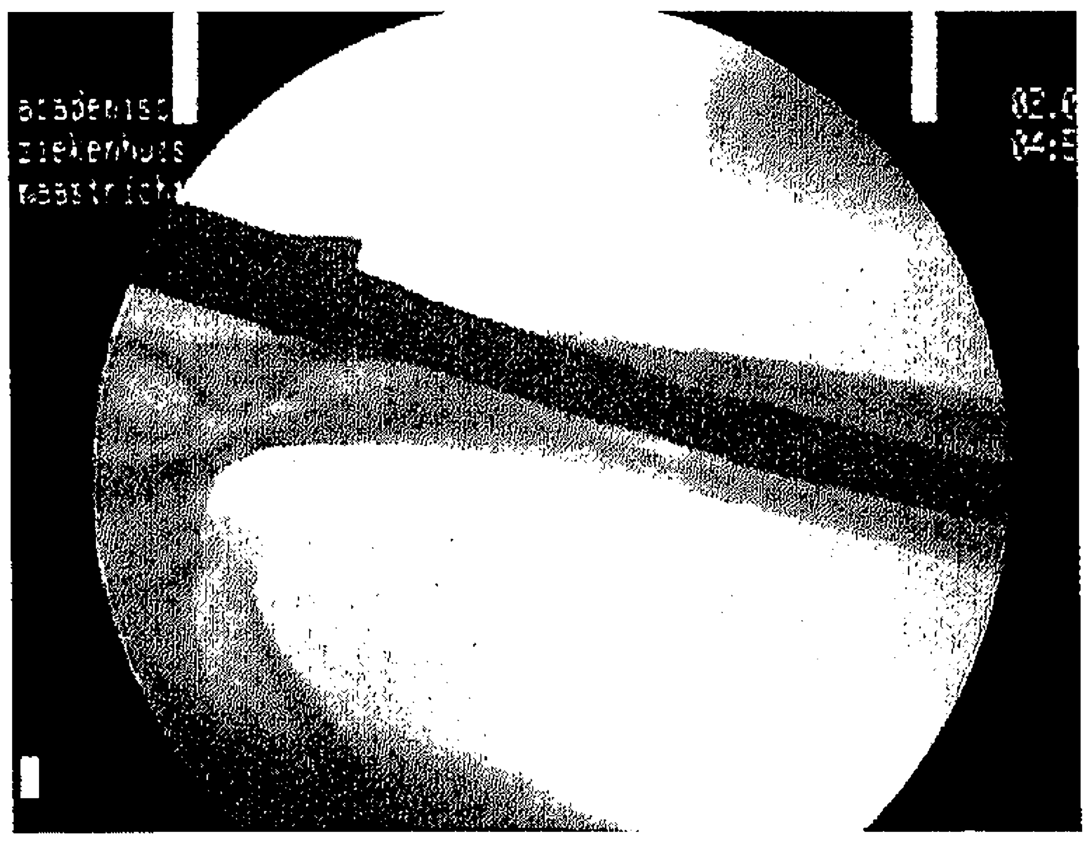

Figure 3-4g: Introduction of the nail and control of proper position of nail.

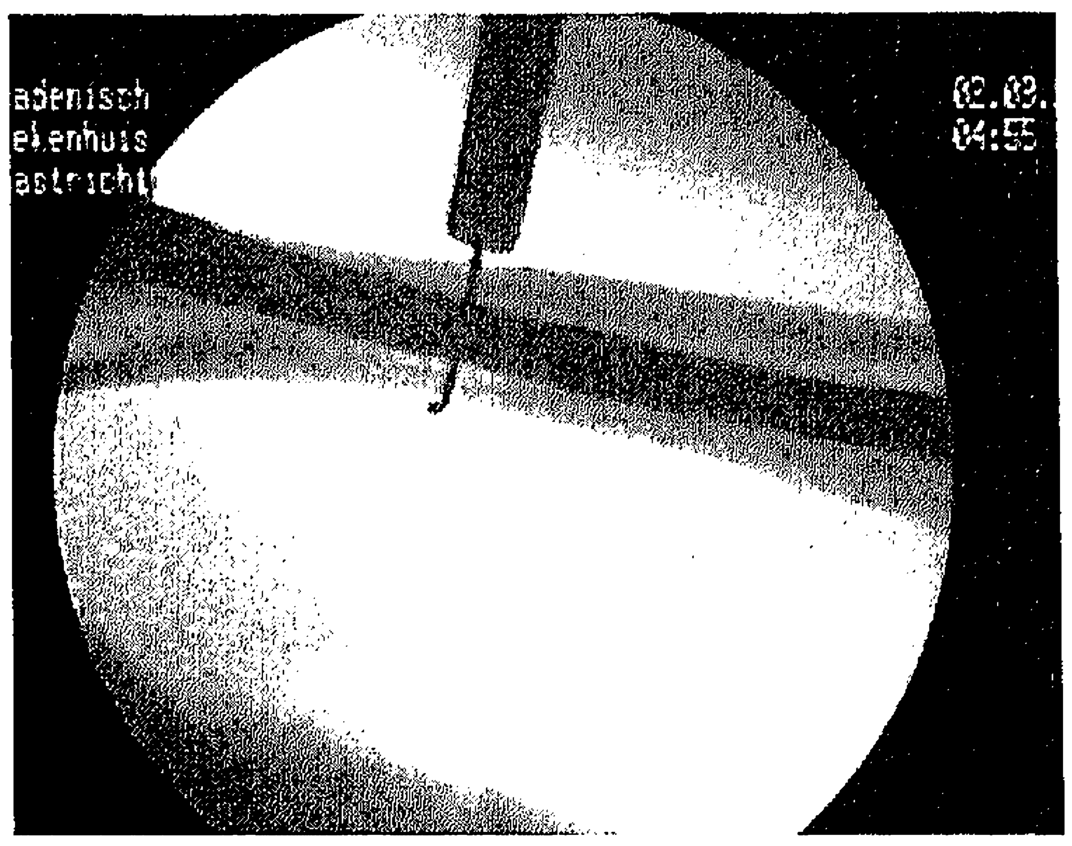

Figure 3-4h: Measuring locking screw length and proximal locking.

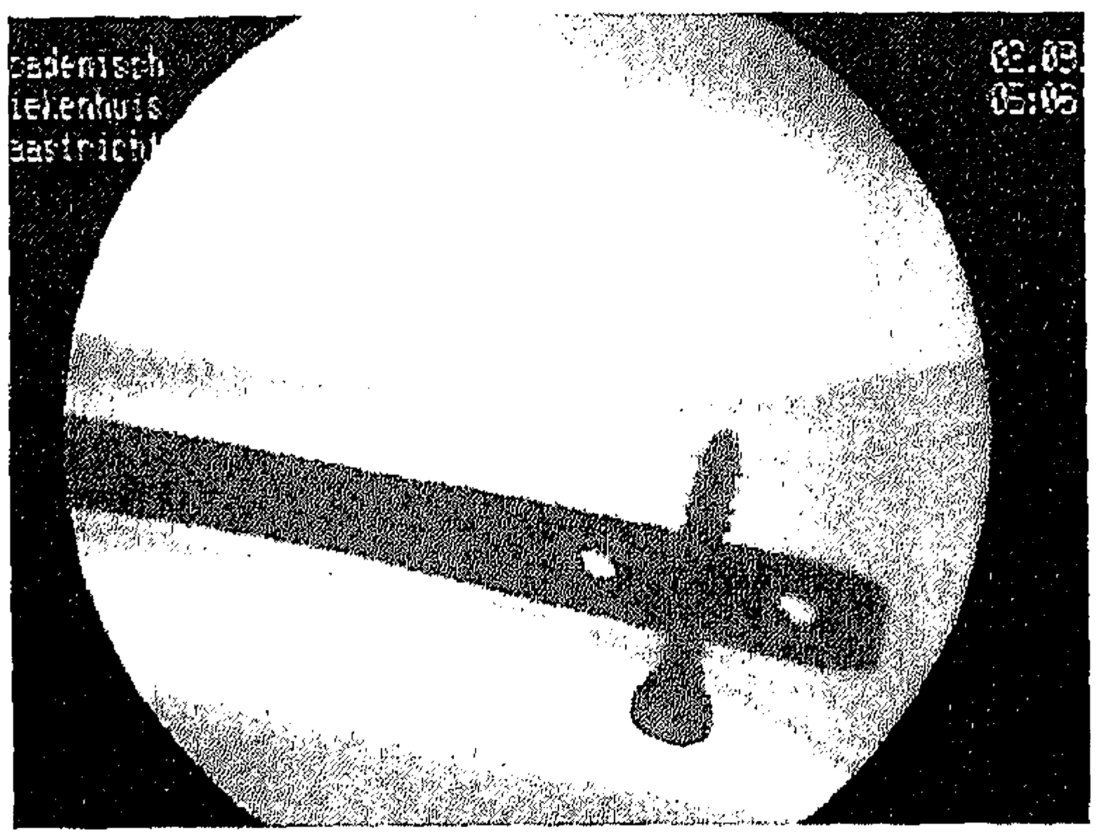

Figure 3-4i: Distal interlocking in free-hand technique.

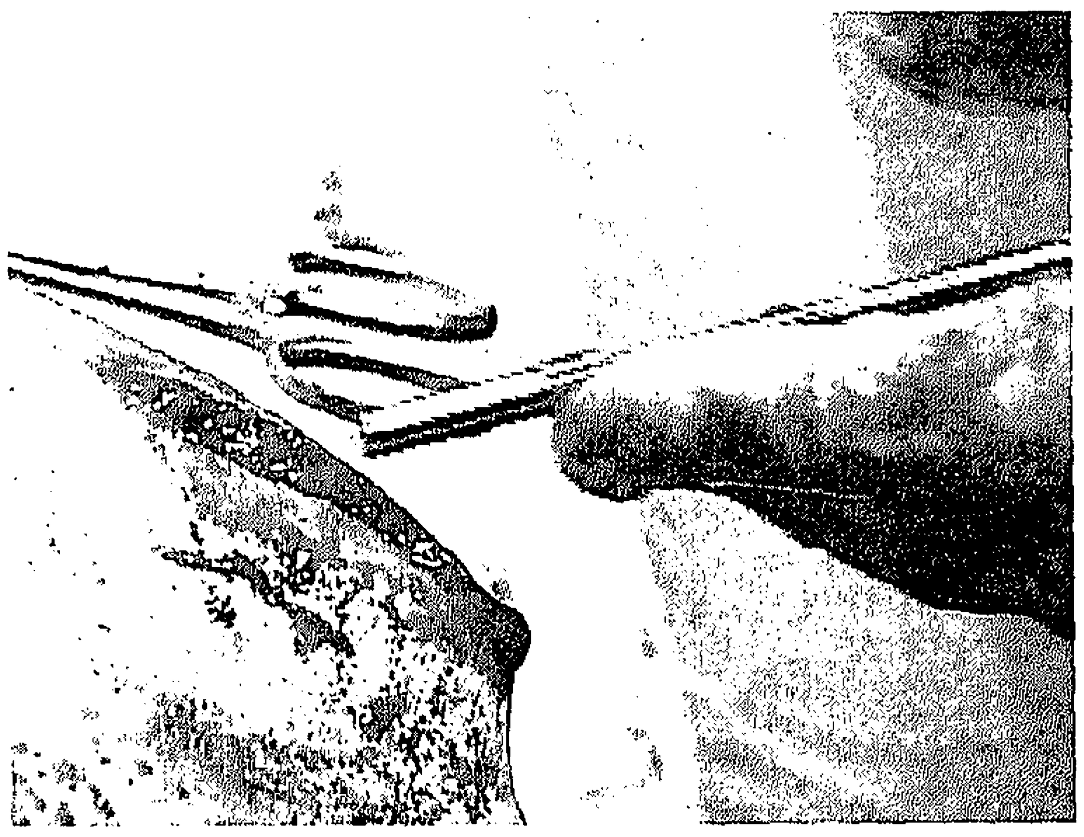

Figure 3-4j: The compression screw is introduced.

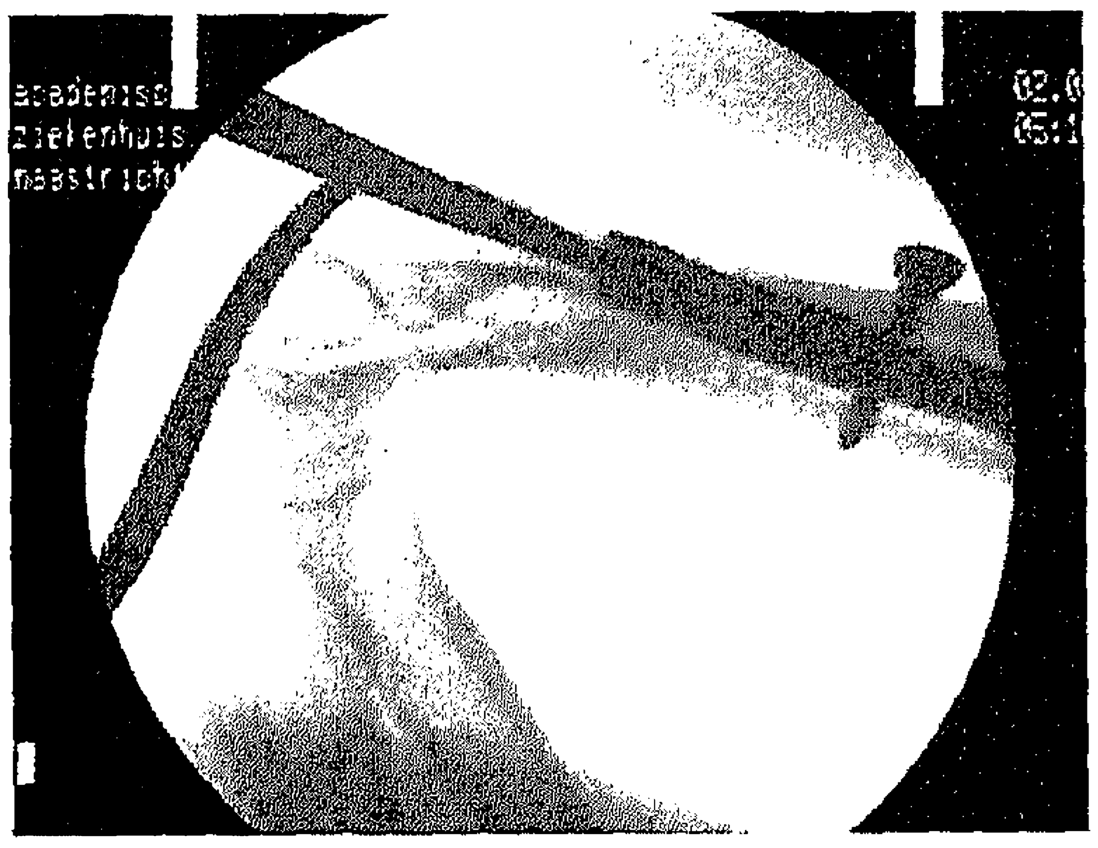

Figure 3-4k: Tightening of the compression screw.

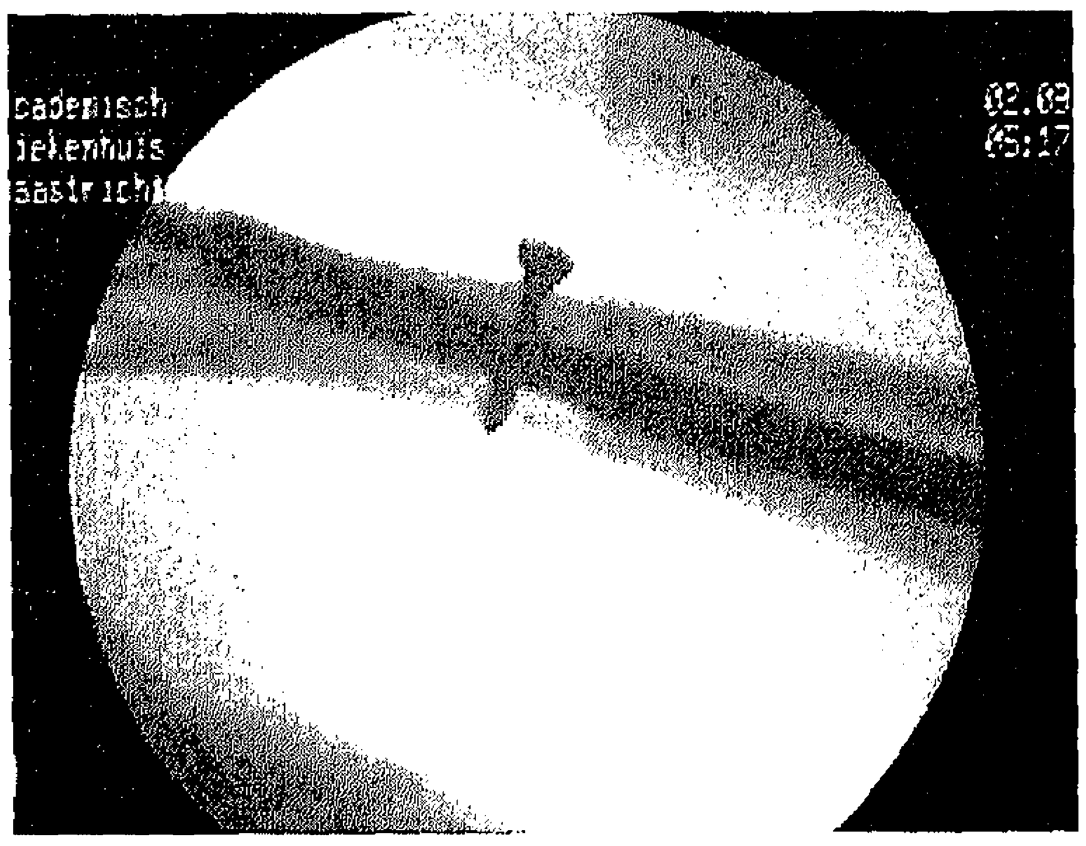

Figure 3-4l: After compression has been applied the relative change of position of the locking screw in the oblong locking hole is clearly visible.

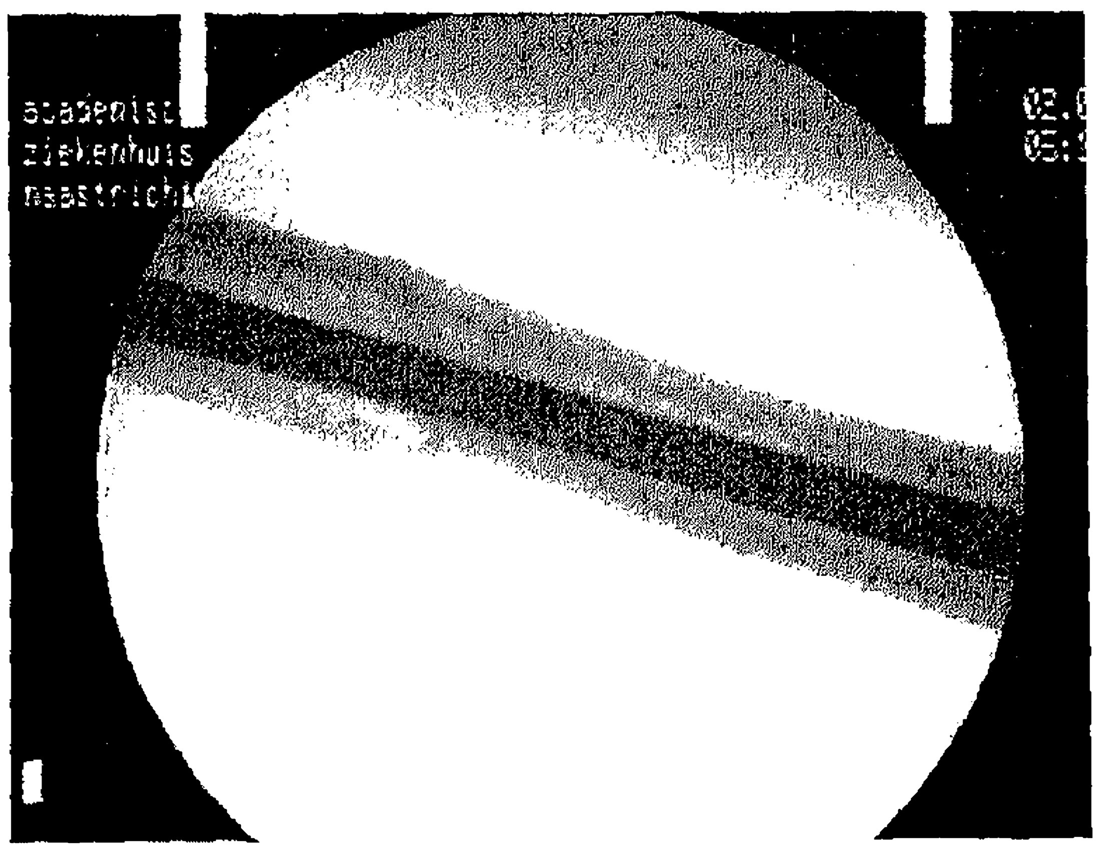

Figure 3-4m: Fracture under compression.

When the access has been prepared sufficiently the guide wire can be introduced and the reaming procedure is started as described above (Figure 3-4 d-e). After introducing the proper nail, the implant is locked (Figure 3-4 f-i). To prevent damaging the axillary nerve the nail tip should be positioned 2 cm below the surgical neck. The quality of the bone in this part of the humerus allows better grip for the locking bolts. Distally interlocking is done through the aiming device in the postero-anterior direction. In the proximal humerus a free hand technique is used. Both postero-anterior and latero-medial locking options are possible. Postero-anterior again is preferred because from lateral there is a higher risk for axillary nerve lesion. If indicated compression can be applied (Figure 3-4 j-m). To prevent the nail from backing out when compression is applied, here also the locking technique as described above can be used.

An alternative technique to open the medullar canal is to drill three holes in the triangle formed by the rim of the olecranon fossa and both columns. These are connected by a bur. The hole is enlarged systematically with the bur until it is about 1 cm wide and 2 cm long. This is necessary to prevent fractures of the dorsal cortex or even distal humeral column while introducing the nail (Figure 3-5).

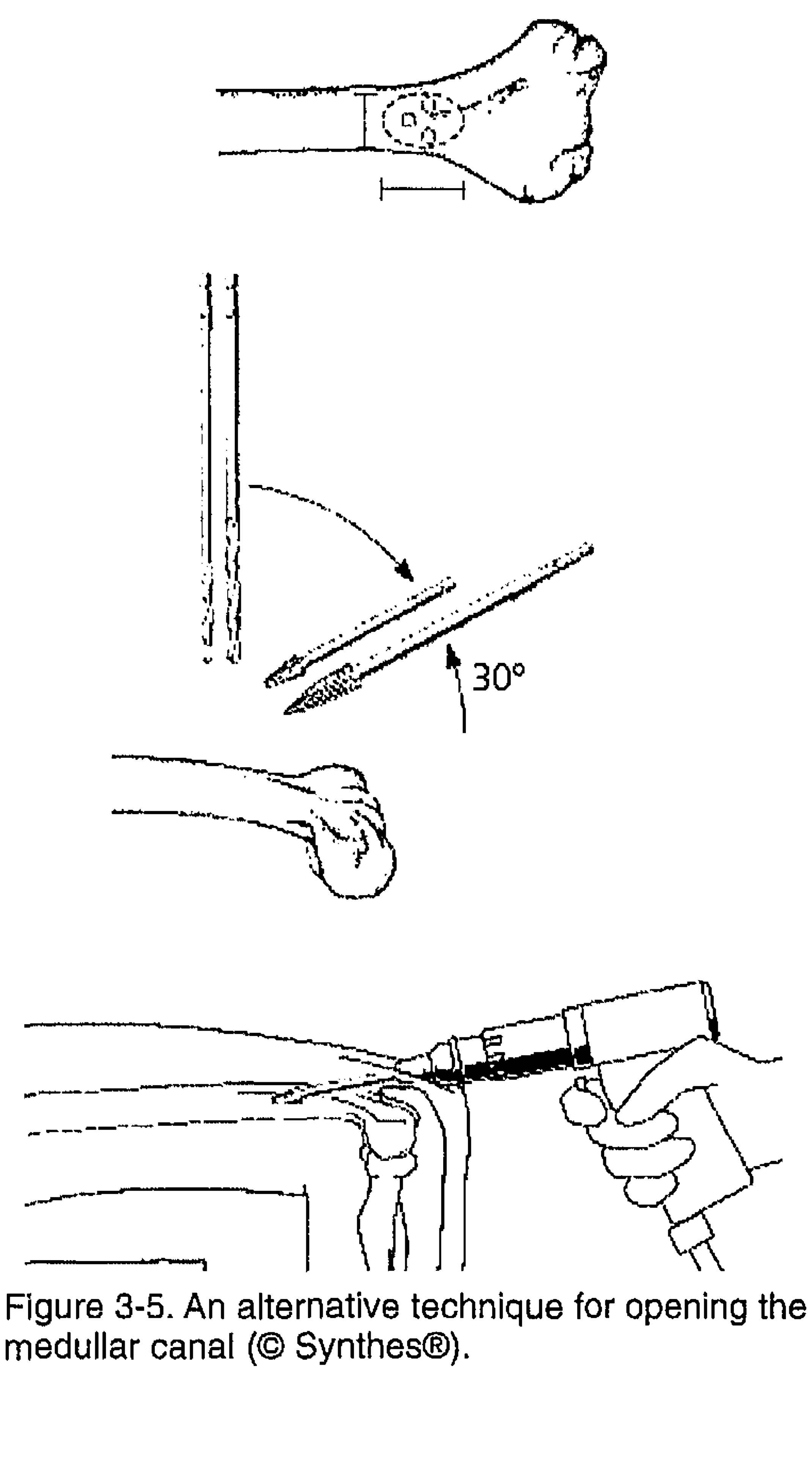

Figure 3-5. An alternative technique for opening the medullar canal (© Synthes®).

CHAPTER IV

Treatment of Humeral Shaft Fractures
An Overview

Non-operative

Humeral shaft fractures in general can be treated non-operatively. Due to other biomechanical demands compared to the long bones of the leg, anatomical reconstruction is not necessary. Shortening till 3 cm is well tolerated and malunion till 30° is easily compensated for by the mobility of the shoulder joint [14,75,95,133]. Different immobilization methods exist. Though providing complete immobilization of the fracture, thoracobrachial plaster casts are uncomfortable and prevent active mobilisation of shoulder and elbow. Lack of hygiene, muscle wasting and shoulder and elbow stiffness are the main disadvantages. There is no evidence in the literature that thoracobrachial plaster casts provide better immobilization than other methods described[38]. These extensive casts are considered obsolete and are no longer part of current practice because they do not fit in the present concepts of early functional treatment. Other plaster casts are the arm-hand cast and the U-slab or sugar tongue splint. These splints are more comfortable and easier to apply. Healing results are good and complication rates low. Non-unions appear in 0,4 till 8% of the cases. However because of complete immobilization of the arm substantial loss of elbow and shoulder function still has to be taken into account. In 10 till 20% of the patients a functional loss of shoulder and/or elbow of 20° to 50° has been reported [12,28,39,62,63,64,75,96,102,134]. André et al. even mentioned functional impairment in 52% [2].

An alternative is the hanging cast (Figure 4-1). The fracture is re-aligned through the weight of the arm and plaster cast. With the hanging cast the shoulder is kept free and can be exercised. Therefore it was promoted as a "functional" bandage in contrast to the thoracobrachial casts. Early movement stimulates vascularisation of the limb and hence fracture healing [15,16]. Arguments against the hanging cast are: a higher risk of non-union especially with transverse fractures because of distraction, the edge of the cast which acts as a fulcrum causing angulation, the insignificant functional treatment and the difficulties with bedridden and obese patients [20,29,95]. Stuart and Hundley reported 93% good to excellent functional results [129]. Ciernik however found even after a mean of 8.5 years, a significant reduction of upper arm mobility in 23 patients [23]. De Morgues et al. reported loss of shoulder function in 11% of 107 cases[32]. Dallek et al. mentioned poor functional results in 7% and secondary surgery because of delayed fracture healing in 15% [28]. Wiedmer mentioned a higher complication rate with hanging casts compared to other immobilizing techniques [144]. Because of the higher tendency to non-union, other authors prefer the U-slab or sugar tongue plaster, especially with transverse fractures.

Despite acceptable healing rates, all off the aforementioned bandages lead to a substantial loss of function of shoulder and elbow. Therefore functional bracing as described by Sarmiento et al. provides for a valide alternative. Functional bracing combines fracture alignment and immobilization with active movement of the arm (Figure 4-2). Compressing the muscles around the humeral shaft by a circular brace

Figure 4-1: Humeral shaft fracture treated with a hanging cast.

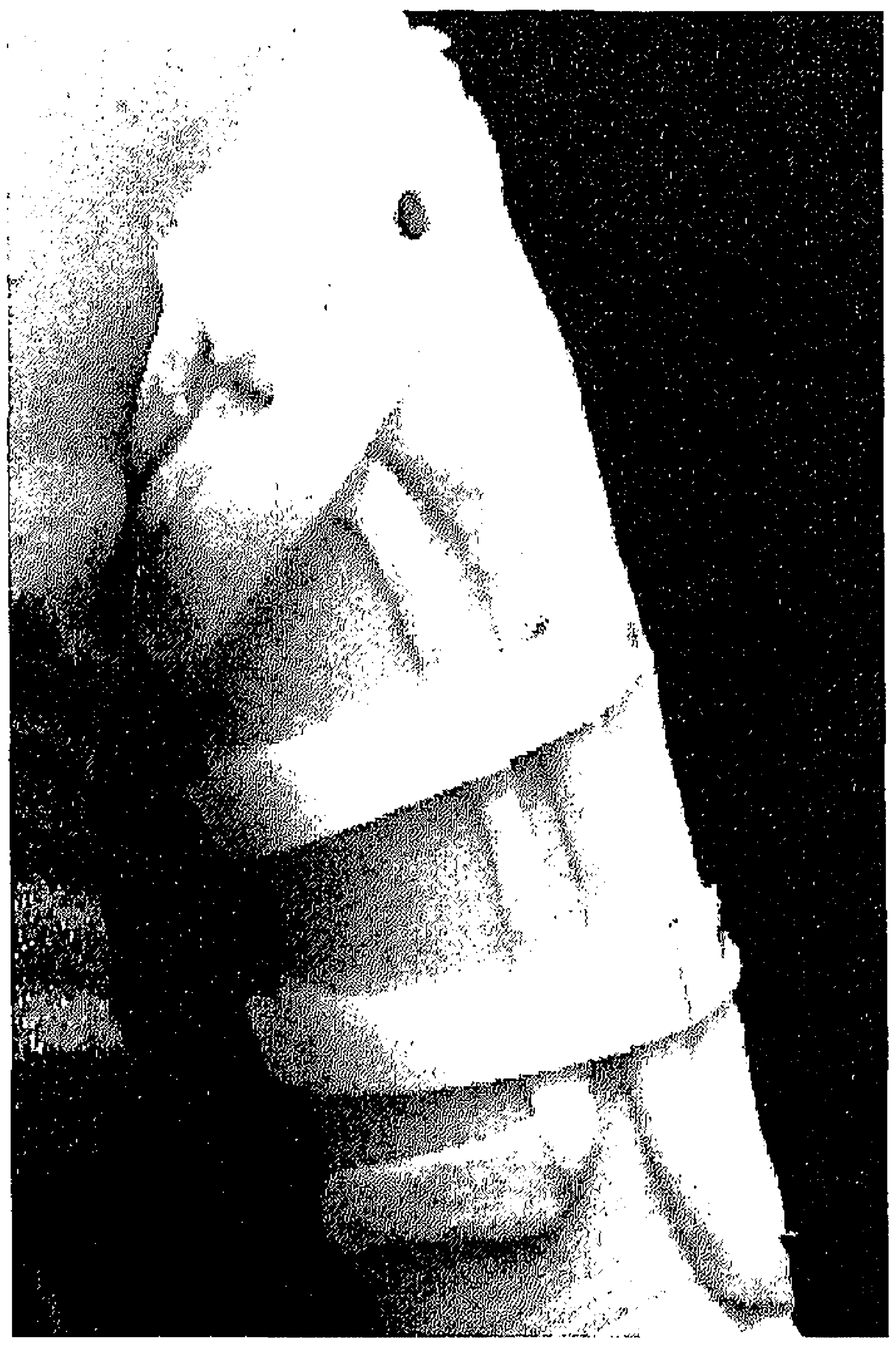

Figure 4-2: The Sarmiento brace as used for treatment of a humeral shaft fracture.

stabilises the fracture through the hydrostatic pressure existing in the different muscle compartments. In combination with the natural tendency of the muscle fibres to recoil after being stretched by gravity, this leads to reposition and apposition of fracture fragments. The adjacent joints are kept free and early functional therapy is possible preventing adhesive capsulitis and muscle wasting. Active movement also provides for a higher vascularisation of the limb creating an ideal environment for fracture healing [85, 120]. Sarmiento reported a healing rate of 98% and good final functional results with a loss of shoulder movement of less then 10°. Results of more then 600 patients reported in 2000 showed a healing rate of 93%. In 11% of the cases a loss of motion of the shoulder and in 7,6% a loss of motion of the elbow was noticed [120, 121]. Other authors could present comparable good results. Non-union rates have varied from 1 to 13%. Loss of shoulder function in 6,3%, but also in 60% of cases has been mentioned. Malunion in varus and loss of external rotation are the most common sequellae after fracture consolidation [35, 42, 58, 71, 77, 79, 84, 105 107, 141, 147].

In a comparison of Sarmiento bracing with U-slab plaster Camden concluded that the brace was the better option in view of healing and functional results [17]. This simple technique with low non-union rates and good functional results, today is considered the standard for non-operative treatment of humeral shaft fractures.

Nevertheless non-operative treatment also has its limits. Foulk et al. mentioned a non-union rate of 39%[43]. Christensen had a failure rate of conservative therapy in 30 of 92 cases (41%) [22].

Plate

Comparative studies between non-operative treatment and plating of humeral fractures concluded that non-operative treatment had superior healing and functional results [76, 81, 116, 133, 134, 142]. Nevertheless indications for operative treatment have been defined.

Bilateral fractures, floating elbow, neurovascular lesions, open fractures, polytrauma, inability to maintain reposition and non-cooperative patients generally are considered indications for operative treatment [93, 122]. Stable fixation allows nursing of the patient and early functional treatment. A plate with interfragmentary compression provides for a strong and stable construction allowing early use of the arm (Figure 4-3). Publications report good healing and functional results. Typical complications with plating are non-union, radial nerve palsy and plate loosening. Non-union rates vary between 0 and 6%. Radial nerve palsies occur in 1,6 till 25%. More experience and refinement of technique could reduce this rate to about 10%. Plate loosening occurs in about 2% of cases. Infection rates vary from 0 to 9%. Functional impairment has been reported in 10 to 26% [2, 5, 6, 27, 30, 55, 56, 57, 89, 99, 100, 101, 102, 103, 115, 136, 144].

Table I shows the results of plate osteosynthesis and its most important complications. Only results of fresh fractures were taken into account. Complications like radial nerve palsy and non-union appear to be high compared to the non-operative techniques. This comparison is considered not entirely correct because the indications for operative treatment are the more complex fractures prone for complication [57, 116, 136].

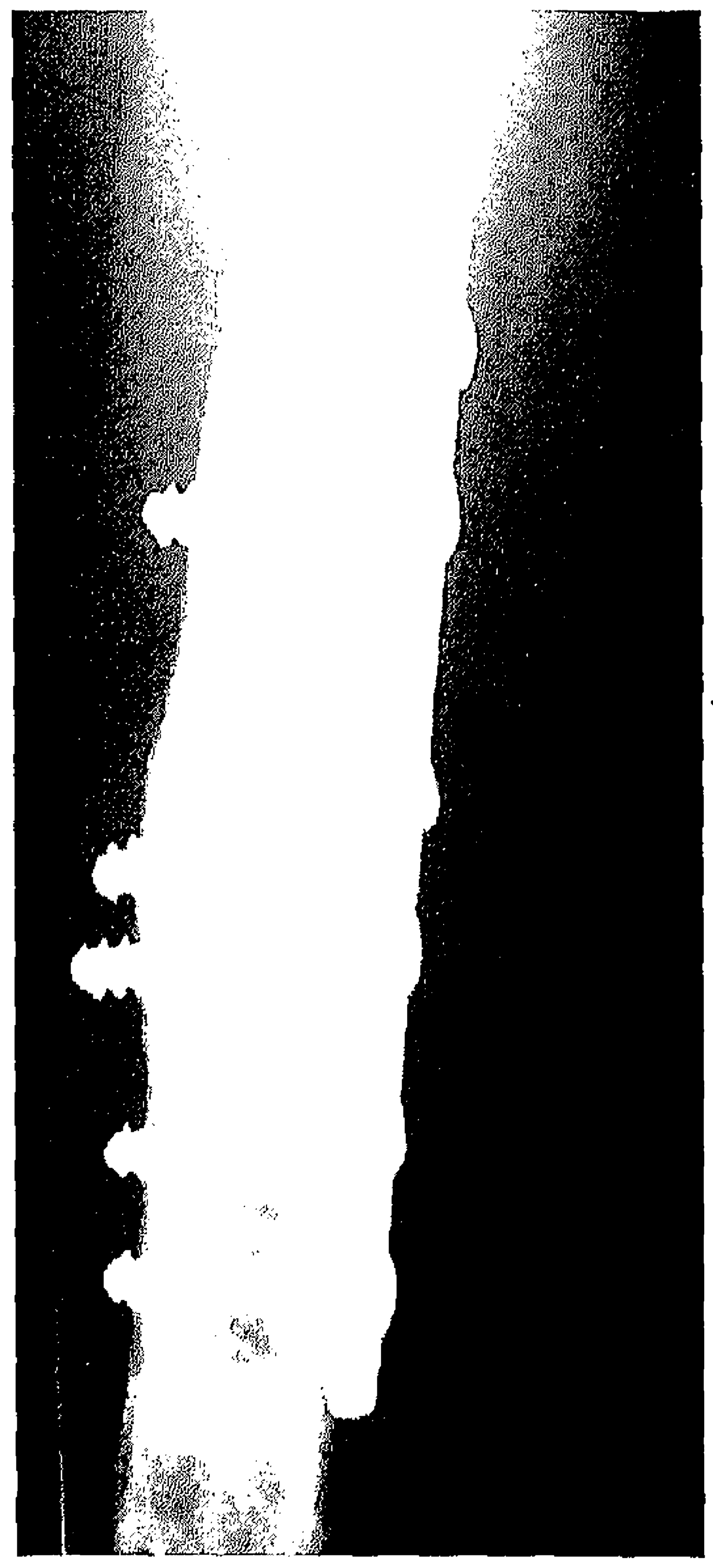

Figure 4-3: Plate osteosynthesis of a humeral shaft fracture.

Table I: Results of plate osteosynthesis with its main complications.

Author	Patients (n)	Acute fract. (n)	NU (n)	Cons. (%)	RNP	Recup.	Infect.	PL
Andre (1984)	50	50	3	94	7	?	4	2
Bell (1985)	34	34	1	97	1	1	1	1
Bèzes (1995)	237	237	3	98,7	14	14	2	6
Dabezies (1992)	44	44	1	97,7	2	2	0	0
Dayez (1999)	36	36	0	100	0	0	0	0
Hee (1998)	35	35	2	94,3	3	3	2	0
Hegelmaier (1993)	25	22	0	100	2	2	0	1
Paris (2000)	156	156	8	94,9	8	7	2	0
Vander Griend (1986)	34	34	1	97	1	1	2	0
Osman (1998)	28	28	2	92,9	2	2	0	0
Kwasny (1990)	84	62	0	100	5	3	3	0
Foster (1985)	45	45	4	91	0	0	2	0
Total	**808**	**783**	**25**		**45**	**35**	**18**	**10**
Percentage			**3,19%**	**96,81%**	**5,57%**		**2,23%**	**1,24%**

NU=non-union, cons.=consolidation, RNP=radial nerve palsy, Recup = recuperation of radial nerve palsy, Infect=infection, PL=plate loosening.

External Fixation

Figure 4- 4 External fixator for treatment of an open distal humeral shaft fracture.

Lambotte was a fervent user of external fixation in the treatment of fractures of long bones and especially of humeral shaft fractures[82]. Nowadays external fixation of humeral fractures is not a standard technique (Figure 4-4). Lack of patient comfort, risk of pin track infection and instability are the main disadvantages. There is also a real risk of radial nerve damage with pin insertion. On the other hand it allows correction of reposition when necessary. Kamhin et al. [69] reported on 8 patients treated with external fixation. Radial nerve palsy appeared to be the main complication. They saw an indication for external fixator with comminution, bone defect, loss of soft tissue, aged patients and more fractures in the same limb. Lenoble et al. [87]

considered secondary displacement and rotational malunion as the main complications.

Polytrauma and open fractures were the main indications. Failure of non-operative treatment and uncooperative patients were secondary indications. Good results in persistent non-union of humeral fractures have been reported with Ilizarov fixators with alternating compression and distraction [83, 86, 104, 108, 118]. The main indication remains the humeral shaft fracture with excessive soft tissue lesion and extreme comminution[8, 33, 69, 118].

Intramedullary techniques

Elastic Nailing

Intramedullary nailing is a good alternative for operative treatment of humeral fractures. Minimal invasive techniques, indirect reposition of the fracture preserving the fracture haematoma and less soft tissue damage are the main advantages. Non-locked nailing as described by Küntscher is known for lack of rotational and axial stability [80, 95, 137]. Elastic nails (EN) like Ender nails or Rush pins and Prévot pins use the 3-point fixation principle of prebended nails [74]. With bundle nailing the entire medullar canal is filled with flexible nails which are stacked together to prevent dislocation of the nails [52]. Good healing results have been reported with non-union rates of 1,2 up till 6,8% [13, 14, 22, 61]. Disadvantages are the lesser rotational and axial stability of the constructs. Distraction of more than 5 mm was the main cause of non-union according to Chen et al.[21]. Hall et al. accepted 10 mm[54]. Most authors recommend additional external immobilization devices such as braces or plaster cast, until the first callus appears. Shazar et al.[125] reviewed 94 humeral fractures treated with elastic nailings. They found a significant difference in healing time between patients with brace and without, suggesting this method of fracture stabilization is not stable enough to allow early functional treatment. In biomechanical studies the instability of elastic nails has been demonstrated [60, 90, 149].

One of the most important causes of complications are the nails themselves. If one nail migrates, the whole construction becomes unstable. Migrating nails compromise shoulder or elbow function and can lead to early secondary interventions for nail removal or re-alignment. Nail migration appears in up to 36% of cases with need for re-interventions in as much as 50% [2, 31, 91, 102, 111]. Compared to the plate Ender nailing requires less operation time and blood loss. Locking nails also lead to less blood loss [19]. Table II represents an overview of publications on elastic nailing. Radial nerve palsies and infection rates are significantly lower compared to the plate.

Table II: Results of elastic nailing with their main complication.

Author	Patients (n)	NU (n)	Cons.(%)	RNP	Recup.	Infect.	Nail Disloc.
Brug (1994)	84	1	98,8	0	0	4	7
Brumback (1986)	58	3	94	0	0	1	20
Champetier (1975)	21	1	95	0	0	0	1
Chen (2000)	118	8	93,2	1	1	3	8
De la Caffinière (1999)	82	6	92,7	0	0	0	24
Dereume (1972)	24	2	91,7	0	0	0	0
Durbin (1982)	25	2	92	0	0	0	0
Hall (1987)	86	1	98,8	2	2	0	8
Hennig (1988)	336	4	98,8	4	4	4	5
Kocher (1980)	42	1	97,6	0	0	0	0
Liebergall (1997)	25	2	92	0	0	0	3
Menger (1985)	27	0	100	0	0	0	0
Osman (1998)	22	1	95,5	1	1	0	8
Rodriguez-Merchan (1996)	30	1	96,7	0	0	0	?
Shazar (1998)	94	8	91,5	1	1	1	3
Total	**1074**	**41**		**9**	**9**	**13**	**87**
Percentages		***3,82%***	***96,20%***	***0,84%***		***1,21%***	***8,10%***

NU = non-union, cons. = consolidation, RNP = radial nerve palsy, recup = recuperation of radial nerve palsy, Infect = infection, Nail disloc.= nail dislocation.

Interlocking Nails

An interlocking nail combines the minimal invasive technique with the rotational and axial stability of a plate. Ward provided Küntscher nails with transverse screws to enhance stabilty for the treatment of humeral non-unions [143]. Seidel introduced the Humeral Locking Nail® (SN) (Figure 4-5). He reported a 100% healing rate and good functional results in his first 20 cases. In a later series of 196 patients he claimed a non-union rate of 0,5% [123, 124]. Other authors reported likewise good healing results with non-union rates of 0 up to 4%. Functional results were satisfactory to excellent according to the Neer score [26, 37, 48, 50, 67, 72, 73, 109, 132]. Riemer did mention that functional recovery took longer than 6 months. In other series however the SN was cause of fierce criticism: complications in more than 50%, problems with the locking system occurred in more then 30%, iatrogenic fractures in more then 20% and non-union in up till 40% of cases. Shoulder function was classified as poor according to the Neer score in 55 to 72% [3, 4, 110, 117, 131, 138]. In a letter to the editor, Habernek [51] withdrew his support of the nail explaining he never had assessed functional outcome properly.

Table III: Results of locked nailing with its main complications.

Author	Nail	Patients (n)	Acute fract. (n)	NU (n)	Cons.(%)	RNP	Recup.	Infect.	Iatr. Fract.
Ingman (1994)	GK	41	21	1	95	1	1	1	4
Ajmal (2001)	RT	33	27	5	81,5	1	1	0	0
Crates (1998)	RT	73	73	4	94,5	2	2	0	0
Cox (2000)	RT	37	37	4	89	0	0	1	1
Petsatodes (2004)	RT	39	36	3	91,7	1	1	0	0
Rommens (1995)	RT	39	39	2	94,9	1	1	0	3
Riemer (1991)	SN	42	29	0	100	0	0	0	4
Crolla (1993)	SN	46	27	0	100	0	0	1	3
Kelsch (1997)	SN	100	81	0	100	0	0	2	7
Thomsen (1998)	SN	48	28	3	89,3	0	0	0	6
Kempf (1994)	SN	48	41	0	100	1	0	1	0
Gaullier (1999)	SN	25	23	1	95,7	0	0	1	0
Lin (1997)	SN / own nail	45	39	0	100	1	1	0	3
Blum (2001)	UHN	84	84	5	94	3	3	0	4
Osman (1998)	SN	22	22	0	100	1	1	0	0
Ikpeme (1994)	RT	30	25	0	100	0	0	0	1
Fernandez (2004)	UHN	51	47	2	95,7	1	1	0	4
Sanzana (2002)	UHN	52	47	0	100	0	0	0	1
Verbruggen (2002)	TLN	70	70	4	96	4	4	4	6
Total		**925**	**796**	**34**		**17**		**11**	**47**
Percentages				**4,27%**	**95,70%**	**1,84%**		**1,19%**	**5,08%**

NU = non-union, Cons. = consolidation, RNP = radial nerve palsy, Recup = recuperation of radial nerve, Infect = infection, Iatrog. Fract. = iatrogenic fracture; GK=Grosse-Kempf tibial nail, SN=Seidel nail, RT=Russell-Taylor nail, UHN=Unreamed Humeral Nail, TLN=Telescopic Locking Nail

The distal locking system with spreading flanges was found to be insufficient and a cause of complications on its own [26, 110, 132, 139]. Biomechanical tests confirmed the low rotational stability of these flanges [49, 60, 146, 149]. The Russell-Taylor® Nail (RT), though primarily developed for antegrade introduction can also be introduced retrograde, both reamed and unreamed. In contrast with the Seidel Nail, different diameters were available from the beginning. Good healing results with minimal complications have been described [25, 65, 106] but non-union rates of up to 30% have been reported also [1, 25, 59]. Retrograde nailing with the Russell-Taylor® nail led to good healing rates of more than 90% and less than 10° loss of shoulder and elbow motion in 89% of cases [113, 114].

The Unreamed Humeral Nail® (UHN®) was developed especially for retrograde introduction. But antegrade introduction is possible. Following the concept of biological osteosynthesis, which demanded as little damage to vascularity as possible, this nail was unreamed [7, 8, 9, 10]. Functional results for shoulder and elbow remained good with loss of 10° in about 89% and 88% respectively [7, 8, 9, 10, 40, 41, 94, 97, 112, 119]. Lin used a self developed nail in the retrograde way with comparable good results [92]. Ingman used a modified Grosse-Kempf tibial nail both in the antegrade and retrograde way. He concluded that retrograde introduction is the better option in order to preserve shoulder function [66]. The most important studies on locked nailing are presented in Table III. To prevent confinding because of different indications only results of acute fractures are presented. Main complications are the iatrogenic fractures. Non-union rate appears to be some what higher compared to plate and elastic nails.

To counter the problems of humeral locking nails with shoulder function impairment, iatrogenic fractures, and complications of interlocking, other nail types have been developed. The Trueflex Nail® is an unreamed nail with a starshaped cross-section. The fluted design provides for rotational stability and axail stability was created by an end cap screw at the end of the nail. [47]. Galagher presented a comparable implant [46]. Another "minimal" implant is the Halder humeral nail which used flexible nails wich were introduced through the nail to provide rotational stability [53]. Reports on clinical and functional results were good but experience with these implants is limited. They never became widely used.

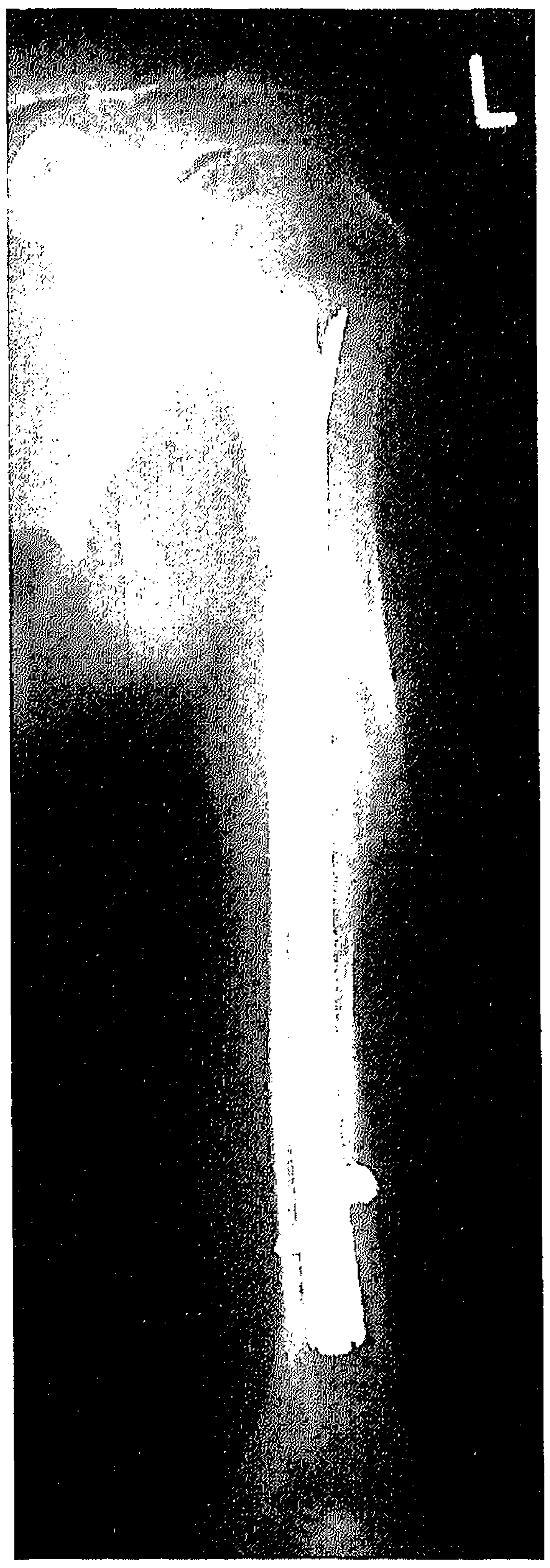

Figure 4-5: Seidel Nail introduced retrograde, the spreaded flanges are clearly visible.

The Marchetti-Vincenzi Nail® is a variation on elastic nailing. The nail is introduced retrograde as a humeral nail with the elastic nails folded together. After positioning of the nail the rods are released and spread out in the medullar canal providing some rotational stability. Good healing results have been described. Problems however were caused by the bulky proximal end of the nails, causing fractures or difficulties especially with nail removal. The stability is comparable with elastic nailing [127, 145, 148].

The Flexnail® is a thin, flexible nail consisting of different links (Figure 4-6). Being highly flexible this nail can be introduced both from distal and proximal without creating the typical tension in the cortical bone leading to fractures. Proximally a complete extra-articular introduction can be chosen. After introduction and interlocking of the nail, the links are "locked" with a special screw, making the nail straight and stiff to achieve stability. First results looked promising but being a modular built implant, the movement of the different links leads to metallosis with local bone reaction causing bone weakening and even nail breakage [70, 129].

The latest development are the so called "inflatable nails", the Fixion®-nails (Figure 4-7). There is no need for interlocking which prevents damage to nerves or tendons and which shortens operation time. A hollow nail provided with four ridges is delivered folded in itself. After the nail is in place it is filled with fluid under a pressure of up to

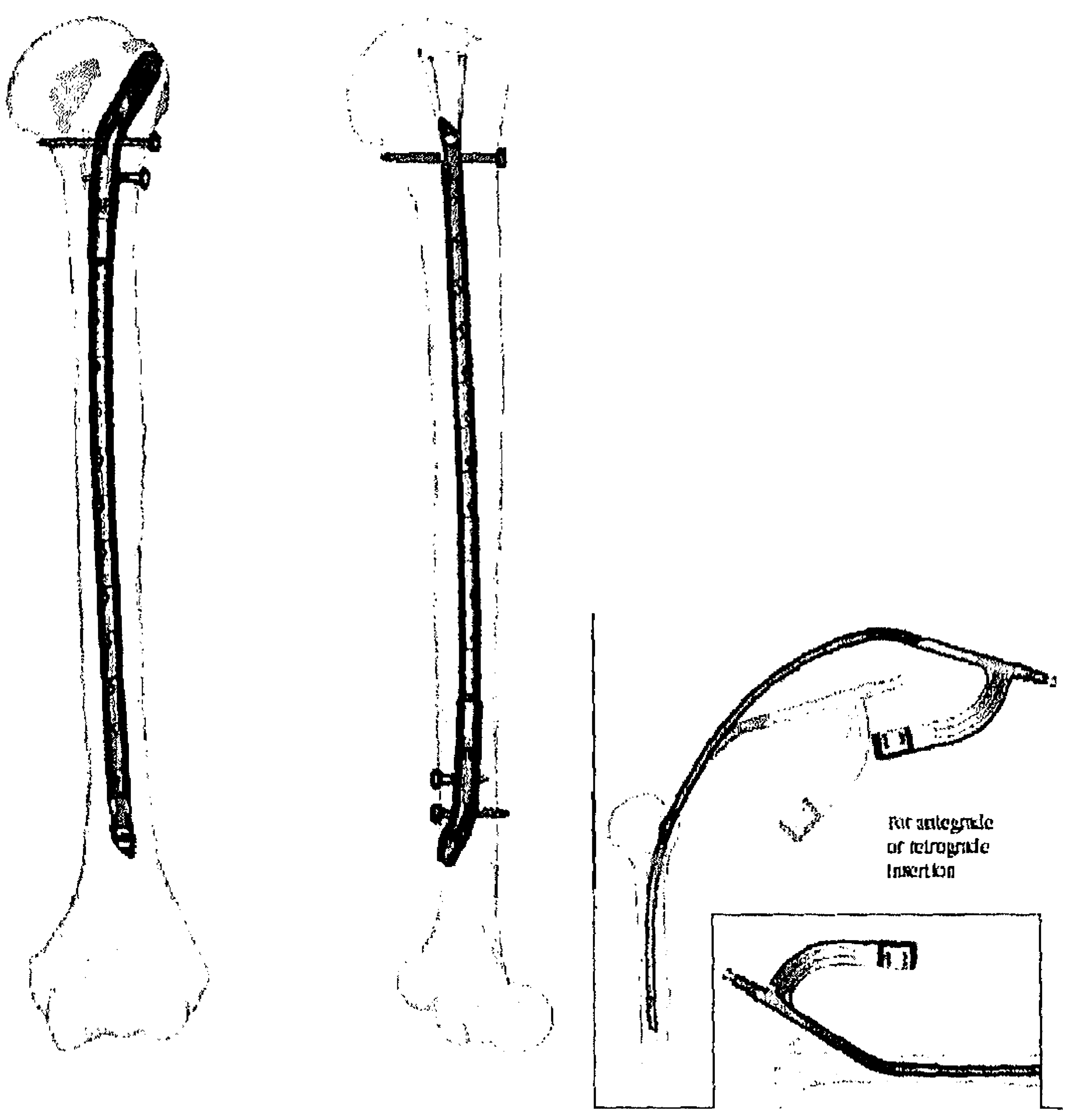

Figure 4-6: The Flexnail® (©Synthes).

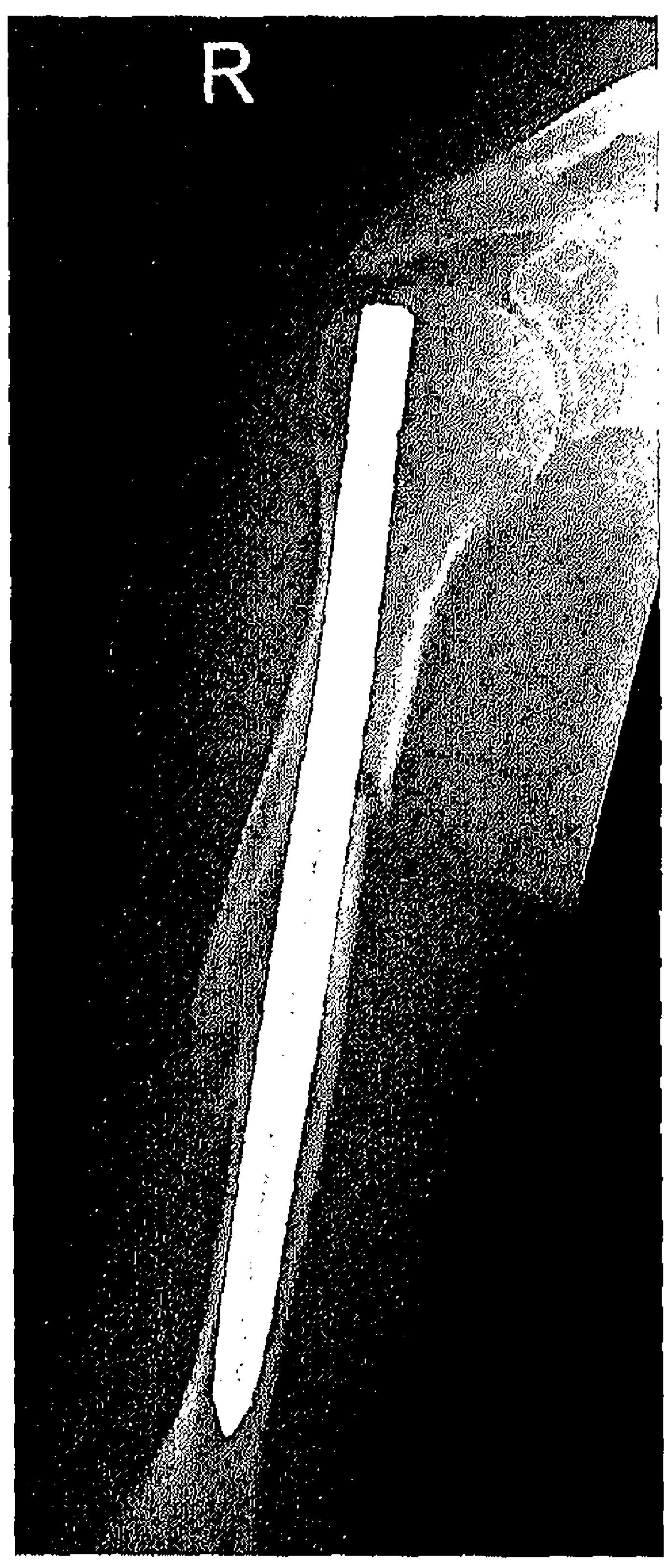

Figure 4-7: The Fixion® Nail.

70 bar. The nail expands and impinges in the medullar canal. Rotational stability is provided through the ridges. Through the circular expansion some axial stability is provided but because no double interlocking is forseen, these nails are biomechanically rotationally inferior to interlocking nails [7]. Clinical results however look promising [45, 68, 88]. One main complication has been reported, namely spontaneous deflation of the nail [128]. Removal of the implants also appears to be difficult.

In the treatment of humeral fractures different options exist. All for them have been reported to have good healing results with few complications. At the same time each of these techniques has been reported having high complication rates. The discussion on optimal treatment of humeral fractures therefore is still going on.

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CHAPTER V

Reamed Nailing of the Humerus
A clinical study with long term functional results

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Submitted

Abstract

Background: To evaluate the treatment of humeral fractures with a reamed locking nail and its long term functional results.
Patients and Method: Seventy-eight patients with seventy-nine humeral fractures were included. It were thirty-five males with a mean age of 42.3 years and forty-three females with a mean age of 70,5 years. Indications were in fifty cases fresh fractures, in seventeen a non-union and in twelve a pathological fracture. After a mean of 57 months functional results of 34 patients could be assessed.
Results : The healing rate for the fresh fractures (n = 48) was 98% in a mean period of 16,2 weeks. Of non-unions 43% healed in 16,4 weeks after one procedure. The mean Neer score in 34 patients was 86 points and the mean Morrey score was 97 points. A lower Neer score was significantly associated with antegrade introduction (p = 0,048) and presence of the nail (p = 0,037).
Conclusion : We achieved good healing results in the treatment of fresh fractures. For the treatment of non-unions, nailing should be combined with a cancellous bone graft. In order to preserve shoulder function a retrograde introduction should be used. Antegrade introduction is recommended for distal fractures only.

Introduction

Though only 1% of all fractures concern the humerus [17, 22, 23, 27], controversies on the treatment remain today. Most authors consider treatment of humeral fractures to be non-operative. In a prospective AO study however, 56% of the humeral fractures were treated operatively [29]. Plate osteosynthesis has been the golden standard for many years but intramedullary locking nails are widely used nowadays. Reaming or not and the introduction site however, are still a matter of discussion. Good results have been obtained with reamed antegrade nailing with the Seidel Humeral Locking Nail® [15, 22, 30]. Its negative influence on shoulder function and its insufficient distal locking system however led to fierce criticism [31, 35, 39]. Antegrade nailing with the Russell-Taylor® humeral nail led to good healing and functional results [10, 20]. High failure rates and functional impairment also have been reported though [1, 9, 19]. Flinkkilä et al. [12] also found a high failure rate and shoulder function impairment after antegrade nailing with different types of nails. Rommens et al. [32, 33, 34] used the Russell-Taylor Nail® and later the Unreamed Humeral Nail® exclusively in the retrograde way as did Lin et al. [24] with the Seidel Nail and a self designed nail. They had superior functional results.

We believe that the introduction of the nail should be determined by the fracture level. To stay extra-articular, nailing should be done retrograde. This applies for the mid shaft and proximal fractures, distal fractures are to be nailed antegrade. For stability a reamed nail should be used. To evaluate this treatment concept with the use of the Telescopic Locking Nail® (TLN®) and its longterm functional results this study was conducted.

Patients and methods

From January 1994 till December 1997 seventy-eight patients with seventy-nine fractures were treated with the TLN® in nine different hospitals in the Netherlands and followed prospectively. At the end of the study period, patient data were analysed. Missing data were completed by reviewing the patient files. They all were treated with the Telescopic Locking Nail® (TLN®). This is a straight nail with a diameter of 7,6 mm. The nail widens to 9 mm at both ends to allow use of 4.5 mm locking bolts. Locking bolts with full thread of this calibre give good purchase in the bone. The distal end was provided with cutting edges to facilitate nail removal. Interlocking is possible through two locking holes oriented in the same plane as the proximal oblong hole and one at right angles with it. The oblong locking hole makes dynamic and static interlocking possible. To give compression over the fracture site, a special axial screw is introduced at the proximal end after dynamic interlocking of the nail. This technique is used with pseudarthrosis and transverse or short oblique fractures. The nail can be introduced both antegrade and retrograde. Because of the 9 mm diameter at proximal and distal ends, reaming is necessary.

There were thirty-five males with a mean age of 42,3 years (SD 19,5 years) and forty- three females with a mean age of 70,5 years (SD 13.4 years). Follow-up time was an average of thirty-four months (SD 25,3 months). Thirteen patients with fourteen fractures were lost early to follow-up: twelve died, eleven of their malignancies and one due to poly-trauma. One patient remained in coma. Thus sixty-five patients could be followed at least till fracture healing.

Fifty were primary treatments, seventeen non- or delayed unions and twelve (impending) pathological fractures. Two fractures were sub-capital, twenty-seven were in the proximal third, thirty-nine were in the mid third and eleven in the distal third of the shaft. In three cases there was a combination of a sub-capital fracture with a shaft fracture. Only the shaft fractures were stabilised.

The fresh fractures were classified according to the AO/ASIF classification. There were twenty-six type A, thirteen type B and eleven type C fractures. Three fractures were open. In two cases grade one and in one case grade two according to the classification of Gustillo-Anderson.

The mean interval between trauma and operation was fourteen days (SD 14,7 days). The delay was due to a primary intention to treat non-operatively. Failure of reposition and patient discomfort were reasons to change to operative stabilisation. Of the seventeen non- or delayed unions, twelve were primarily treated with a brace, two with Rush pins, one with a plate, one with a Seidel Humeral Locking Nail® and one with an external fixator. The mean time between trauma and operation was twenty-one weeks (SD 10,57 weeks).

Of the twelve pathological fractures, the primary tumour was in three cases a Grawitz tumour, in two cases a M.Kahler, a breast tumour and a lung tumour respectively and a thyroid, melanoma and oroparyngeal tumour each in one case. All patients with (impending) pathological fractures obtained sufficient relief of pain and restoration of function. As they were all lost early to follow-up they are not further discussed.

After a mean follow-up of fifty-seven months (SD 11,6 months), thirty-four patients were re-examined. The Neer and Morrey score were used to evaluate the results of shoulder and elbow function respectively. To test for differences between the original patient group and the re-examined group, Chi-square and (because of the asymmetry of the distribution of the outcome variables) Mann-Whitney-U tests were used. No formal sample size was determined because this was a pragmatic study and all eligible patients were included.

Results

Nails were introduced antegrade forty-four times and retrograde thirty-five times. In one case interlocking was only distal. In a total of thirty-five patients a compression screw was used. Of the seventeen secondarily operated patients a compression screw was used in thirteen cases. In sixty cases the operation time was properly registered. The mean operation time was 103 minutes. Of these 61,6% took less than ninety minutes. In 35% the operation time varied between forty-five and sixty minutes.

Per-operative complications were need for open reposition in five patients and seven iatrogenic fractures due to nail introduction. In one patient a fissure of the distal humeral shaft occurred during antegrade introduction. The other six occurred with retrograde introduction. In four cases it concerned a fracture of the dorsal cortex without consequences. In the other two a fracture through the medial condyle was stabilised with a circlage wire and screws respectively.

Five patients had a pre-operative neural lesion: three radial palsies and two plexus lesions. The radial palsies resolved spontaneously. Four patients developed a radial palsy postoperatively. These also resolved spontaneously.

We encountered four infections, three deep and one superficial.

Fifty-five out of sixty-five fractures (84%) healed after one procedure. Of the forty-eight fresh fractures that could be followed till healing, forty-seven (98%) healed within a mean of 16,2 weeks (SD 8 weeks). One patient developed a non-union. Because of her age and bad general condition she was not re-operated.

Eight of the seventeen non-unions (47%) healed after one procedure within a mean period of 16,4 weeks (SD 4,3 weeks). In nine patients a re-operation with cancellous bone graft was deemed necessary. Five refused a re-operation because of good function without pain. Four underwent one or more secondary procedures with cancellous bone grafting and eventually achieved healing. In total we had a healing rate of fifty-nine out of sixty- five patients (90%). Healing results are presented in Table 1.

Table 1: Healing results in 59 of 65 patients.

Weeks	Acute fractures (n=47)	All (n=59)
6	2	2
6-8	4	4
8-12	15	18
12-16	8	11
16-24	12	13
>24	6	11

Implant failures were minimal. In two cases (2,5%) a nail migrated and in four (5%) a locking bolt failed. One nail broke out and another bent, both after an adequate trauma. The former was replaced. In two patients a locking bolt, and in three the nail was removed early due to complaints of pain, which also impaired joint function.

Full use of the arm was possible after an average of eight weeks (SD 3,40 weeks) in thirty-six of the cases with fresh fractures.

The function of shoulder and elbow was not specifically determined. The function was assessed in forty-eight cases. In 79% of them a loss of shoulder function of less then 30° in any direction was found. For the elbow this was 100%. Thirty-four patients were re-examined after a mean follow-up of fifty-seven months (SD 11,6 months). This group consisted of nineteen men and fifteen women. The mean age was fifty-four years (SD 20,84 years). The mean age of the men was forty-one years (SD 14,82 years), the mean age of the women was seventy-one years (SD 13,1 year). Twenty were nailed antegrade, fourteen retrograde. Six of the patients belonged to the non-union group, twenty-eight to the fresh fracture group. In seventeen cases the nail had been removed: nine after antegrade and eight after retrograde introduction. The reasons for nail removal were: protrusion into the joint (n=2), pain caused by implant material (n=9), sustained infection (n=1) and patient request (n=5).

There were no significant differences between the original patient group and the re-examined group in terms of sex, fracture type, fracture localisation, way of introduction, complications or radial nerve lesion (Chi-square). Consolidation period, loss of function and operation time also did not differ (Mann-Whitney U). The older age group however was significantly under represented ($p = 0.004$). This is explained through the fact that the elderly patients are the first to be lost to follow-up. We however found no correlation between age and Neer or Morrey score. The age distribution was in keeping with the total study group. We therefore considered this group as a statistically representative sample for the whole patient group.

The mean Neer score was eighty-six points (SD 14 points) and the mean Morrey score was ninety-seven points (SD 6 points). The Neer score was in twenty-three cases (67.5%) excellent, in three (9%) satisfactory and in eight (23,5%) a failure. All the patients with nail removal scored excellent. In the antegrade group were two failures, in the retrograde six. For elbow function thirty-three patients (97%) scored good to excellent, and one (3%) scored fair. Functional results are presented in Table 2.

Only the group with the fresh fractures was considered in the further analysis because the pseudarthrosis group was too small and function might also be impaired through longer immobilisation before operation. The Neer score in this group of twenty-eight patients was satisfactory with a mean of eighty-six points (SD 15 points). Seventeen were nailed antegrade and eleven retrograde. There were nineteen (68%) excellent, three (11%) satisfactory and six (21%) failures. In the antegrade group were five failures, in the retrograde group one (Table 3).

The elbow function was excellent with a mean of ninety-seven points (SD 6 points). Twenty-four (86%) scored excellent, three (10%) good and one (4%) fair. In the antegrade group sixteen patients scored good to excellent, in the retrograde group all scored excellent (Table 4). A lower Neer score was statistically significantly associated with antegrade introduction (p = 0,048, two tailed) and presence of the nail (p = 0,037, two tailed).

Table 2: Functional results according to the Neer and Morrey score in 34 patients available for follow-up.

Neer score		**Morrey score**	
Excellent	23	**Excellent**	27
Satisfactory	3	**Good**	6
Unsatisfactory	0	**Fair**	1
Failure	8	**Poor**	0

Table 3: The Neer score in relation to the way of introduction in 28 of 50 patients with acute humeral fractures available for follow-up.

Neer score	**All (n=28)**	**Antegrade (n=17)**	**Retrograde (n=11)**
Excellent	19	9	10
Satisfactory	3	3	0
Unsatisfactory	0	0	0
Failure	6	5	1

Table 4: The Morrey score in relation to the way of introduction in 28 of 50 patients with acute humeral fractures available for follow-up.

Morrey score	All (n=28)	Antegrade (n=17)	Retrograde (n=11)
Excellent	24	13	11
Good	3	3	0
Fair	1	1	0
Poor	0	0	0

Discussion

Technique

Most of the humeral fractures are simple fractures. Only 16% are multi-fragment or comminuted fractures [27]. Tytherleigh-Strong et al. [37] found in only 10,4% C-type fractures. About 6% of all humeral fractures are open [6, 27, 29, 37]. The age distribution is bimodal: young males and elderly females are most affected. In 60% the patient is older than fifty [37]. The epidemiological data of this series are conform the literature. In the male group the average age is lower than in the female group. Most fractures are closed and are caused by low energy trauma. Three fractures were open. Only nine out of fifty (18%) fresh fractures were type C. We found a rather high percentage of elderly: 72% is older then fifty.

Open fractures, neurovascular lesion, floating elbow, bilateral fractures, polytrauma, pathological fractures, pseudarthrosis and inability to maintain reduction are considered absolute indications for operative treatment of humeral fractures [5, 10, 13]. These indications contain a negative selection of humeral fractures prone for complications [18, 38]. If treated with an intramedullary interlocking nail, these "problem fractures" need a stable implant. The TLN® for the humerus is specifically intended for these situations [14]. The TLN® is a straight nail. Most humeral nails have a curvature at the proximal end. In our opinion this curved design is more out of tradition than out of anatomical consideration. The humeral intramedullary canal is straight with an anterior bend in the distal part. It has a trumpet like form, broader at the proximal end and smaller at the distal end. It can easily accommodate a straight implant. We have not encountered any design related problems introducing the TLN®.

The overall occurrence of seven iatrogenic fractures (8,8%) is comparable with the series of Rommens et al. [32, 33] with about 8% and Robinson et al. [31] and Ingman et al. [21] with 10%. Varley mentioned even 22% [39]. Six of the fractures occurred with retrograde introduction in the supra-condylar region. Two fractures through the medial epicondyle, needed stabilisation with a circlage wire and screws respectively. The other four were fractures through the dorsal cortex without need for stabilisation. One was a fissure in the distal shaft occurring with antegrade introduction. Possible causes are not sufficient reaming of the shaft or portal and the application of too much force while introducing the nail. With a retrograde introduction one should make the access sufficiently wide. Introducing a reamed 9 mm nail demands reaming of the introduction site to 11mm. Reaming of the shaft should be at least 10mm. Extra care has to be taken with introduction of the nail to prevent unnecessary stress in the supra-condylar region or the shaft. Small rotating movements are useful while introducing the nail. Radial nerve involvement or interposition of soft tissues and difficult alignment in the pseudarthroses were reasons for open procedures. Loosening of locking bolts (5%) occurred in osteoporotic bone. In the literature rates of up to 10% have been reported [20].

Fresh Fractures

The primary treated fractures had a healing rate of 98%, comparable with the literature [4, 15, 20, 22, 24, 28, 32, 33, 34]. The reaming of the humerus did not affect fracture healing. It might even benefit the bone healing through the endogenous cancellous bone graft, which is generated by reaming. Several authors confirm the beneficial effect of reamed nailing on long bones [3, 11, 36]. We see no reason why this should be different for the humerus. There was no difference in healing between antegrade and retrograde introduced nails as suggested by Hems et al. [19] and Flinkkalä et al. [12]. We do prefer the retrograde introduction to stay extra-articular. The fractures located in the distal third on the other hand are preferentially approached from proximal. According to Lin et al. [25] it would be better bio-mechanically to stabilise distal fractures from distal and proximal fractures from proximal. We agree however with Brumback et al. [6], Hall et al. [16] and Ward et al. [40] that it is better to keep the introduction site as far away from the fracture as possible to prevent destabilisation of the smaller fragment through iatrogenic fractures. The fact that in this series forty-four patients are treated with antegrade introduction is due to the personal preference of the different surgeons. Most fractures in this series were mid-shaft. All proximal fractures however, were approached from distal and vice versa.

Secondary Interventions

Of the seventeen secondary interventions for non-union, only eight (43%) healed after one procedure. This was an unexpected result. In the treatment of humeral non-union the classic technique described, is decortication, bone grafting and rigid plate fixation with compression. These principles, except for the decortication, apply for the technique used. The reaming provides for the necessary cancellous bone graft and the straight 9 mm nail gives stability due to its contact with the cortices and the strong locking bolts. Extra stability is gained by compression, applied through the compression screw.

Nine patients were proposed a new operation with cancellous bone graft. Four achieved healing eventually after a second procedure with cancellous bone-graft. Five of them refused because they could use their arm without restriction or pain, despite a non-union. Other authors also seem to have problems with healing in secondary use of the humeral locking nail. In the series of Rommens et al. [34] the eventual healing rate of this specific patient group remains unclear. Hems et al. [19] describes only four secondary interventions of which two failed. Loitz et al. [28] had a failure in one out of five non-unions. Ajmal et al. [1] reported only one healing out of six non-unions. In a series of forty-one delayed and non-unions treated with retrograde nailing and compression over the fracture, Linn et al. [26] describes a 95% healing rate. All of these but two delayed unions were treated with a cancellous bone graft. Treatment of non-unions with an intra-medullary nail alone seems therefore insufficient. It should be combined with an open cancellous bone graft.

Complications

Four infections (5%) is comparable with other series. Two occurred after a secondary procedure. In one case the pathological fracture was stabilised in spite of an infection after a bone biopsy, the other was an infected non-union. The third case was a superficial infection treated with antibiotics, and the fourth was a multi-injured patient in which an acetabulum fracture and the humeral fracture were stabilised in the same session. He was treated with nail removal and reaming of the medullary canal, followed by a new osteosynthesis after resolution of the infection.

Post-operative radial palsies in 5% of the cases is comparable with the literature where rates of up to 9% have been described [39]. No permanent radial nerve palsies have been seen after using the TLN®.

Functional Results

Since the introduction of humeral intramedullary nails, much more attention has been paid to functional results. Other techniques used in the treatment of humeral fractures however also have their effect on shoulder and elbow function. Bell et al. [2] found eight out of thirty-four patients (23%) with loss of shoulder motion. Van der Griend et al. [38] had in 9% of the cases an elbow function between 20° and 115°. Heim et al. reported loss of function in 12,7% of the cases [18]. Chapman et al. found in a prospective randomised study a significant correlation between loss of elbow function and plate osteosynthesis[7]. Loss of shoulder function was significantly correlated with antegrade nailing.

The overall functional results are considered good with a mean Neer score of 86 and a Morrey score of 97 points. In the fresh fracture group 79% had at least a satisfactory result. For the Neer score satisfactory to excellent results in 29 till 88% of the cases have been reported [19,20,22,31]. Six failures (21%) however is very high. This group consists of four elderly patients with concomitant lesions such as radial palsy (n=2), sub-capital fracture (n=1) and pseudarthrosis (n=1). Of the two younger patients one had an extensive soft tissue lesion, the other one was a psychiatric patient with no obvious reason for his or her poor outcome. The significant correlation between direction of introduction of the nail and the Neer score confirms the negative influence of antegrade nailing on the shoulder function, even after a longer period. Flinkkilä et al. and Chapmann et al. also found a significant correlation between antegrade nailing and disturbed shoulder function [7, 12]. Other studies confirm the negative influence of antegrade nailing on the shoulder function [1, 9, 19, 21, 31, 35, 39]. The Morrey score was good to excellent in 97%. The long-term impact of retrograde nailing on the elbow clearly is not as profound as with antegrade nailing. Other studies confirm this [4, 21, 25, 28, 32, 33, 34].

We also found a positive correlation between presence of the nail and a lower Neer score independent of introduction site. This could be explained by protrusion of the nail into the shoulder joint. All protruding nails had been removed during follow-up however and protrusion in the shoulder joint with retrograde nailing is very unlikely and didn't occur in this series. In the case of properly countersunk antegrade nails or retrograde introduced nails, functional impairment and pain might be caused by prominent locking bolts, as suggested by other authors [1, 9, 12, 20]. This was the case in nine of the fourteen patients who had their nail removed. Though normally nail removal is not necessary, it should be considered in the case of functional impairment through migration of the nail into the joint or because of pain caused by implant material.

Conclusion

Reamed nailing of the humerus with the Telescopic Locking Nail® leads to good results as shown in the healing rate of 98% for the fresh fractures. The treatment of non-union however remains a problem despite the stability of the implant and the use of compression. For this specific problem we recommend the use of the TLN® in combination with an open cancellous bone graft.

Antegrade nailing does have a negative influence on shoulder function. Depending on the fracture localisation a retrograde introduction should be chosen whenever possible. Only in the case of a distal fracture antegrade nailing is advised.
Long-term results show also the beneficial effect of nail removal on shoulder joint function, even in cases with a properly countersunk nail.

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CHAPTER VI

Reamed Nailing of Fresh Humeral Fractures
Longterm results in 77 cases

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Summary

To evaluate the Telescopic Locking Nail® (TLN®) a retrospective analysis of prospective gathered data was conducted. A total of 77 humeral fractures was included. There were forty-four females and thirty-three males with a mean age fifty-five years (15-87 years). In fifty-one patients the nail was introduced in the antegrade way, in twenty-six in the retrograde way. We found a primary healing rate of 96 % after a mean of 18,6 weeks (6 - 61,6 weeks).

After a mean follow-up of thirty-five months (2-86) forty-seven patients were re-evaluated concerning their shoulder and elbow function. The mean Neer score was 88 points (45-100), the mean Morrey score was 97 points (72-100). In the antegrade group (n = 51) the mean Neer score was 86 points (45-100) and in the retrograde group (n = 26) 91 (60-100).

The good healing results together with the good functional outcome suggest the Telescopic Locking Nail® is a suitable implant for the treatment of humeral fractures. The lower Neer score in the antegrade group confirms the impact of antegrade nailing on shoulder function.

Introduction

Intramedullary locked nailing is widely used nowadays in the treatment of humeral fractures. After the introduction of the Humeral Locking Nail® by Seidel[27] several reports with excellent healing and functional results have been published [11, 17, 21]. The disturbance of the rotator-cuff and hence its negative influence on shoulder function and the high complication rate [22, 26, 28, 32] were important arguments in favour of retrograde introduction and other nailing systems [2, 6, 9, 14, 15, 16, 18, 23, 24]. The discussion whether to introduce antegrade or retrograde or whether to ream or not remains today.

Polytrauma, bilateral fractures, chain fractures, open fractures, neurovascular lesions, pseudarthrosis, pathological fractures and inability to maintain reduction are generally considered absolute operation indications [2, 3, 6, 8, 20, 31, 32]. These indications form a negative selection of humeral fractures, prone for complications [13, 31]. Therefore a stable implant is mandatory. The Telescopic Locking Nail® (TLN®) was conceived to treat these "problem" fractures [10]. It is a straight nail with a central diameter of 7,6 mm. Both ends have a diameter of 9 mm to allow full threaded locking bolts of 4,6 mm. An oblong locking hole at the proximal end allows dynamic or static interlocking. Through a special screw compression can be exerted. The nail can be introduced retrograde or antegrade. The 9 mm ends make reaming necessary.

To evaluate the Telescopic Locking Nail® in the treatment of acute humeral fractures this study was conducted.

Patients and methods

To evaluate the TLN® a prospective multicentre trial was conducted in nine different hospitals in the Netherlands. In a retrospective analysis of these prospective gathered data seventy-seven patients with seventy-seven fresh humeral fractures were included. There were thirty-three males and forty-four females. The mean age was fifty-five years (range 15-87 years). The mean age in the female group was sixty-seven years (23-87 years). The mean age in the male group was forty years (15-82 years). Seven patients were lost to follow-up before fracture healing.

The fractures were classified according to the AO. There were forty-six type A, twenty type B and eleven type C. The fracture was located in the proximal third in twenty-five patients, in fourty-two in the middle third and in ten patients in the distal third (Figures 1 and 2).

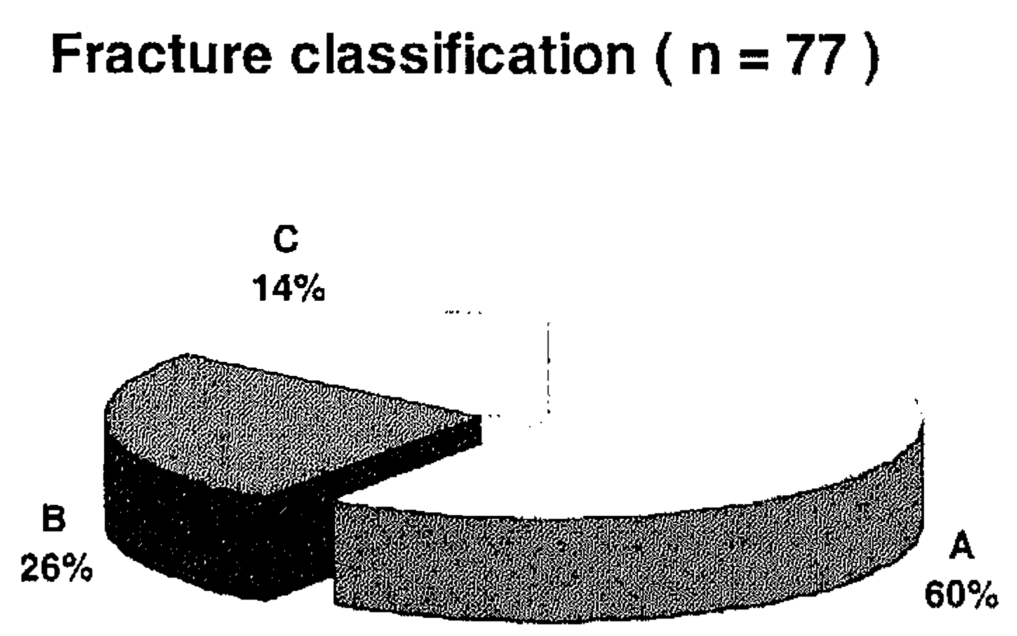

Figure 1: Fracture classification according to the AO of the 77 fractures

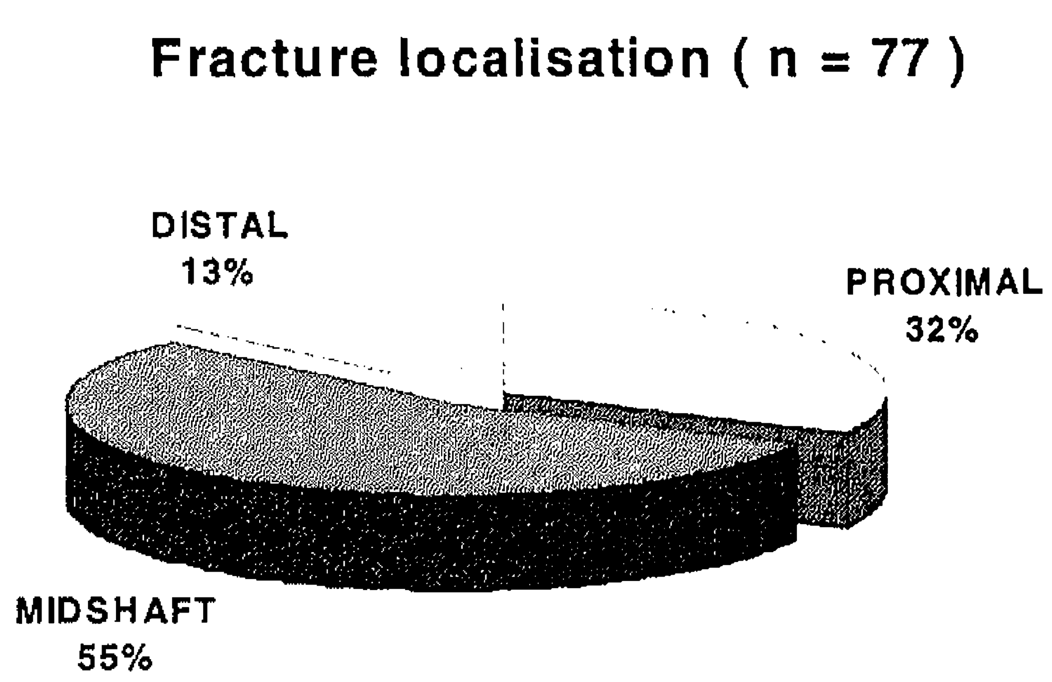

Figure 2: Localisation of 77 fractures of the humera shaft.

The trauma mechanism was in eight patients a polytrauma, in sixty-eight a monc lesion, of which five also due to traffic accidents, and in one case a crush trauma of the forarm.

Seven patients had an open fracture, four grade I and three grade II according tc Gustillo-Anderson. In five patients soft tissue damage was encountered, four times grade I and once grade III according to Tscherne-Oestern.

Six patients had a primary nerve lesion, two times a plexus lesion and four times a radial nerve palsy. The mean delay between trauma and operation was twelve days (range 0-63 days).

The nail was introduced antegrade fifty-one times and retrograde twenty-six times In twenty-nine cases compression was applied.

After a mean follow-up of thirty-five months (range 2-86 months) forty-seven patients were re-evaluated concerning their function. For the shoulder the Neer score was used, for the elbow the Morrey score.

Results

Peroperative complications were iatrogenic fractures in six patients. Only one needed stabilisation. Open reposition was applied in seven patients, two because of radial nerve palsy, five because of difficult reposition due to soft tissue interposition.
Postoperative complications were four radial nerve palsies, four infections and one early re-operation because of protrusion of the nail in the shoulder joint.

Of the seventy patients that could be followed till fracture healing, sixty-seven (96%) healed within a mean of 18,6 weeks (range 6-62 weeks). The overall healing rate was sixty-nine out of seventy (99%). Two patients needed one or more reinterventions to come to consolidation eventually. One patient wasn't re-operated because of her bad general condition.

Forty-seven patients (67%) were evaluated concerning their shoulder and elbow function between two and seven years after the first operation. The mean Neer score was 88 (range 45-100) points.This is considered satisfactory. Of these patients thirty-three scored excellent, five satisfactory, four unsatisfactory and seven were a failure. The mean Morrey score was 97 (range 72-100) points. This is considered excellent. Thirty-five scored excellent, nine good and three satisfactory. There were no failures. Percentages are presented in Figures 3 and 4 .

To have better sight on different treatment modalities the groups with retrograde introduction and antegrade introduction were analysed separately.

In the antegrade group thirty-one out of fifty-one patients were scored. The mean Neer score was 86 (range 45-100). This is satisfactorey according to Neer. Twenty patients scored excellent, three satisfactory, three unsatisfactory and five were a failure (Figure 5). The Morrey score was a mean of 96 (range 72 -100).This is excellent. Twenty-two scored excellent, six good and three satisfactory (Figure 6).

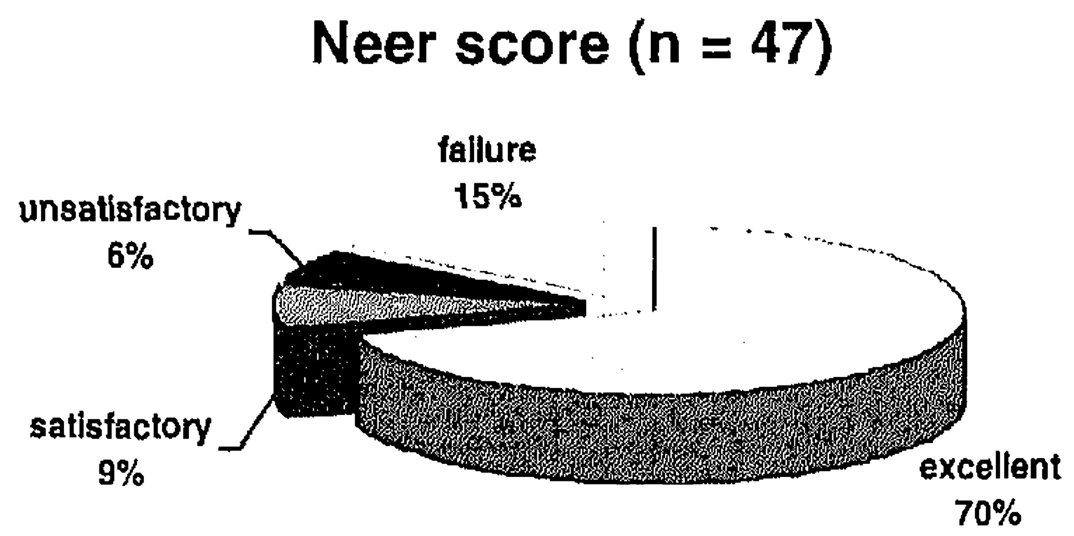

Figure 3: Functional results of the shoulder according to the Neer score in 47 patients.

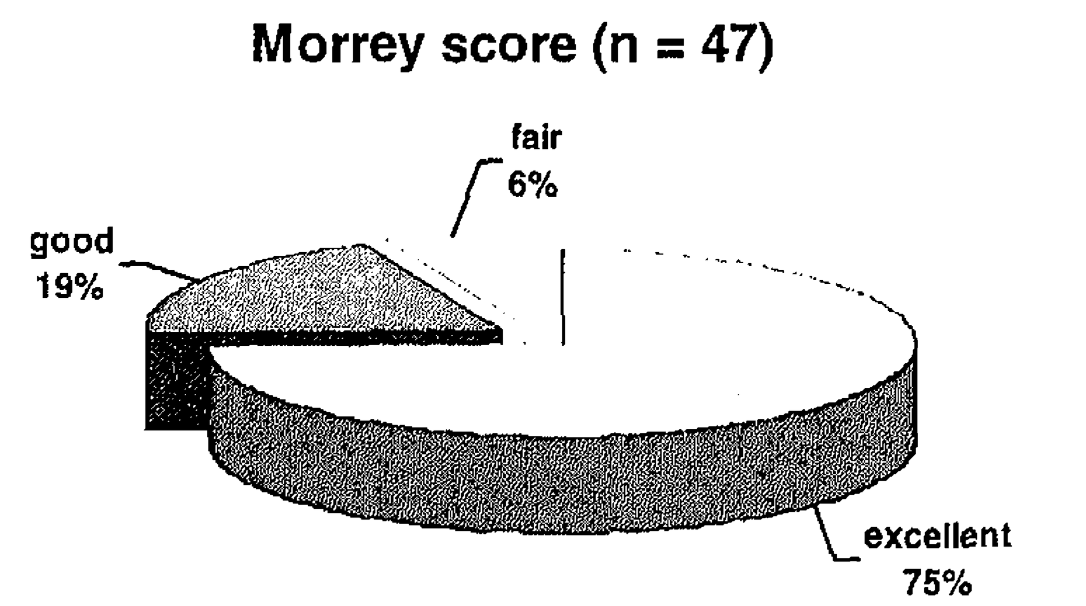

Figure 4: Functional results of the elbow according to the Morrey score in 47 patients.

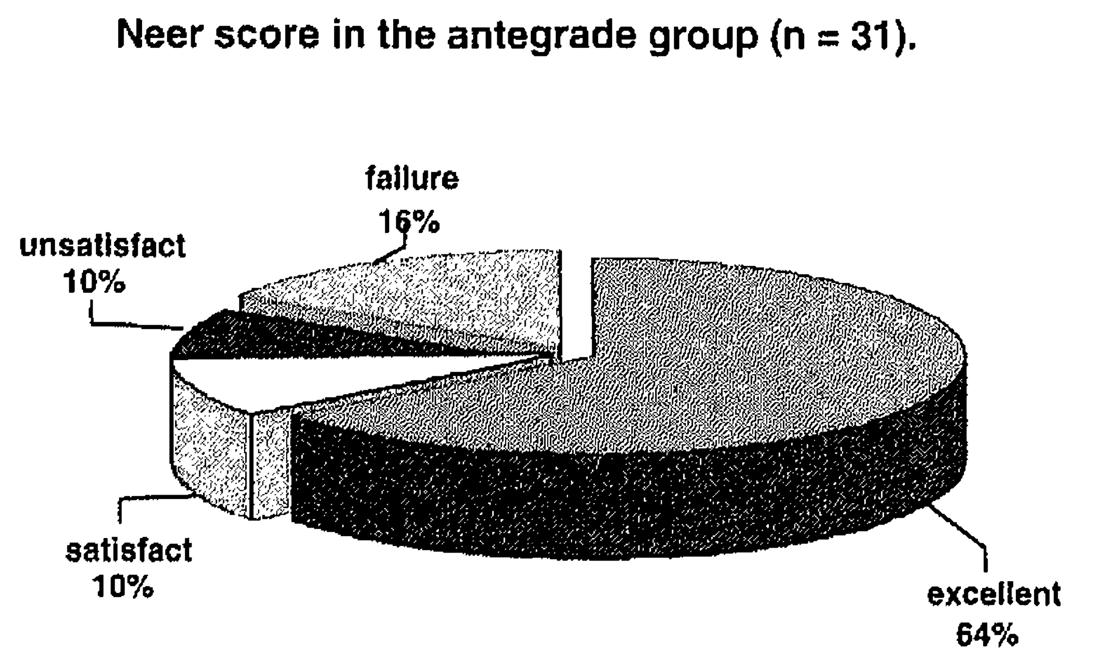

Figure 5: Shoulder function in 31 patients treated antgrade according to the Neer score.

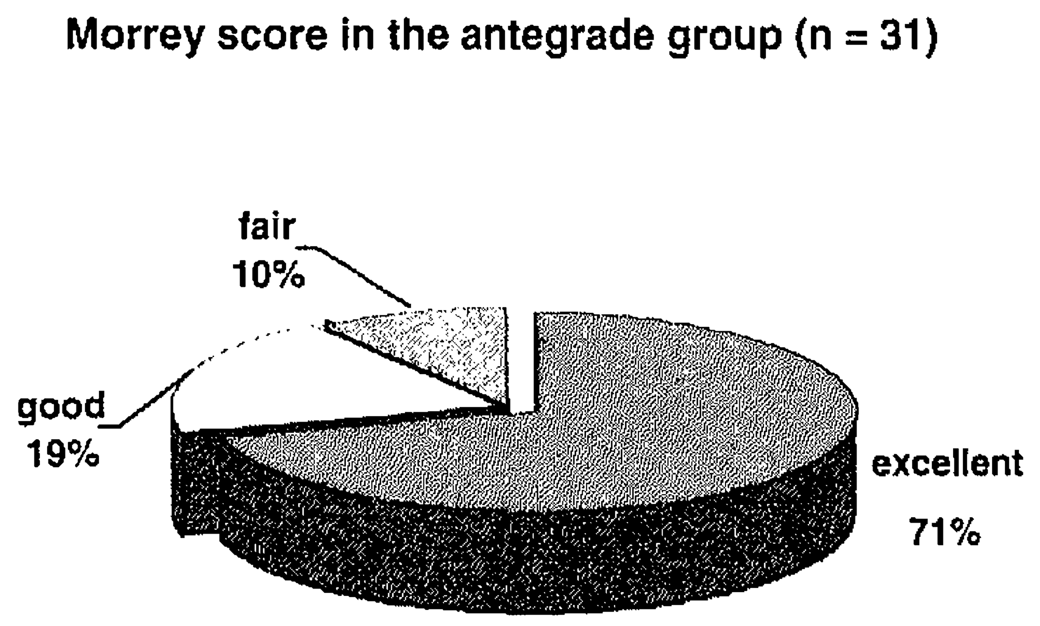

Figure 6: Elbow function in 31 patients treated antegrade according to the Morrey score.

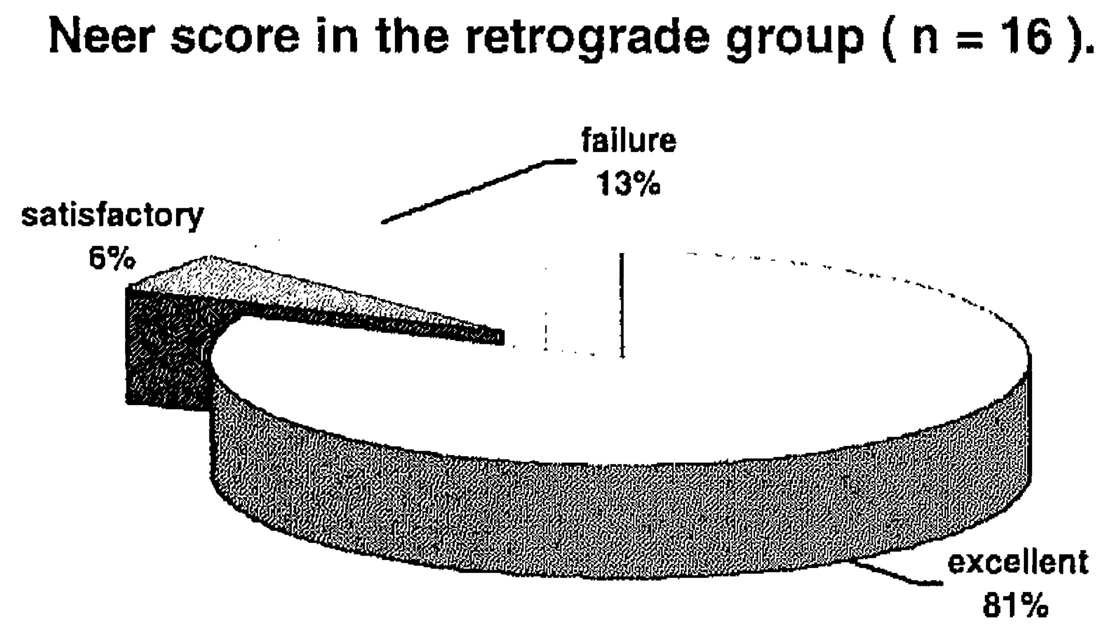

Figure 7: Shoulder function in the retrograde group according to the Neer score in 16 patients.

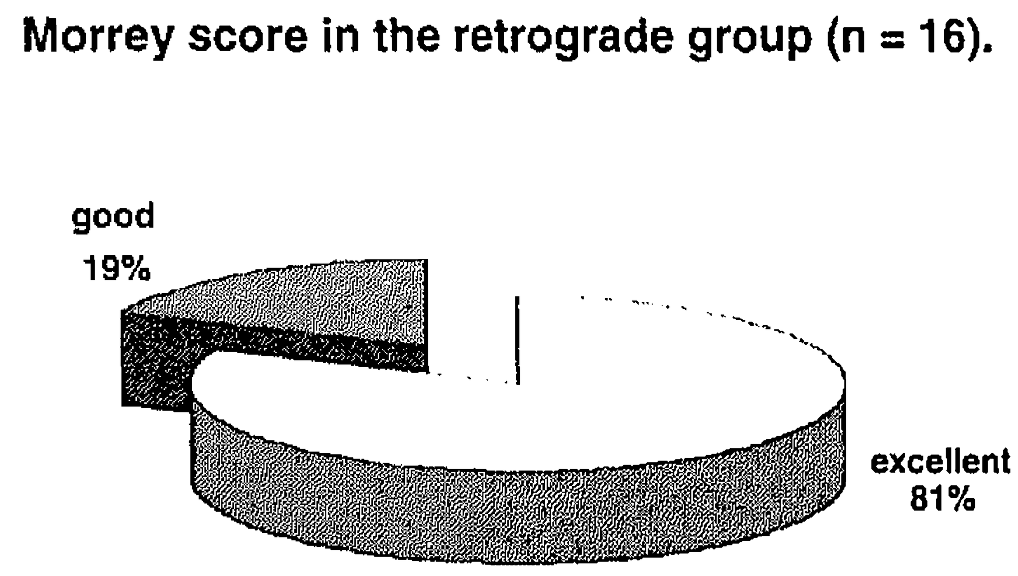

Figure 8: Elbow function according to the Morrey score in 16 patients

In the retrograde group sixteen out of twenty-nine patients were evaluated. The mean Neer score was 91 (range 60-100). This is excellent according the Neer score. Thirteen scored excellent, one satisfactory, and two were failures (Figure 7). The mean Morrey score was 98 (range 89-100). This also is excellent. Thirteen scored excellent, three scored good (Figure 8).

Discussion

The treatment of humeral shaft fractures is still under discussion. This is remarkable as the humeral shaft fracture represents only three percent of all fractures [32]. Most of the time it concerns low energy lesions. This is reflected in this study. Comminutive fracture types occur only in about 18% of the cases. We found 14% C-type fractures. Most fractures also were isolated low energy lesions. The age distribution is bimodal. The younger male and the older female are the most affected groups [4, 30].

In comparison to other implants, the TLN® is a straight nail. We have not encountered any design related difficulties in introducing this nail. The humeral medullary canal has a trumpetlike shape,wide proximally and narrower distally with a volar angulation. A straight nail easily can be introduced from distal or proximal [18, 34]. We prefer the retrograde introduction to stay extra-articular [2, 18, 23, 24, 25]. The fact that in this series 51 patients were nailed antegrade is due to the personal preference of the different surgeons in different hospitals. Most fractures were midshaft. All proximal fractures however were nailed from retrograde and vice versa. Linn et al.[19] suggest that it would be biomechanically better to nail from the shorter into the longer fragment. We agree in this with Ingman et al., Hall et al. and Ward et al. [12, 16, 33] who advise to nail from the longer into the shorter fragment. It prevents destabilisation of the smaller fragment through iatrogenic fractures. In our series we encountered almost 8% iatrogenic fractures. Only one needed stabilisation. Five were caused in the same institute, demonstrating the learning curve of intramedullary nailing.

The primary healing rate of 96% is comparable to other series which present rates between 90 and 100%. Apparently the reaming hasn't any negative effect on the fracture healing, it might even benefit from it. This has been described for tibial and femoral nailing [1, 7, 29]. We see no reason why this should be different for the humerus. Postoperative complications are comparable to the literature. The infection rate is 5%. Postoperative radial palsies, we had in 2,6% of the cases. All recovered completely.

The functional results for shoulder and elbow of this series are good. Comparison with other series is difficult. Most authors use different systems to evaluate the function and not always the precise moment of evaluation during follow-up is mentioned. Furthermore most series consist of a mixed patient group of acute and pathological fractures and secundary procedures for non-unions. The lower Neer score for the antegrade introduced nails suggests its negative impact on shoulder function. Other studies confirm the negative influence of antegrade nailing on the shoulder function [5,8,14,16,26].

We conclude that the treatment of fresh humeral fractures with the TLN® has good healing results. Reaming has no influence on the healing rate. It allows the use of a thicker, more stable implant. Also the functional results are good. The differences between antegrade and retrograde nailing for the shoulder function suggest it is better to introduce the nail retrograde depending on the fracture localisation. The impact of retrograde nailing on the elbow function is almost non-existent.

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CHAPTER VII

Humeral fractures in the elderly
Treatment with a reamed intramedullary locking nail

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Abstract

In the elderly patient co-morbidities combined with lower functional demands lead to a tendency of non-operative treatment. Fast recuperation of function however is mandatory in the elderly patient to prevent loss of independency and social functioning. In a retrospective follow-up study 40 patients with a mean age of 75 (range 60-87) years were included. They all were treated with a reamed intramedullary nail. 21 patients were operated on after a mean of 6 (range 0-16) days, nineteen after a mean of 28 (range 9-63) days after primary intention of non-operative treatment. Five patients (12.5%) were lost to follow-up.The primary healing rate was 94% (33/35) after a mean of 17 (range 6-61) weeks. 14% (5/35) needed a reoperation of which two because of healing problems. Functional results could be assessed in 18 patients: the mean Neer score was 90 (range 45-97) points and the mean Morrey score 98 (range 74-100) points. The relative functional score was 94 (range 89-101) and 100 (range 97-100) points respectively. All functional scores were independent of introduction site and time of treatment.

Based on these results we conclude that treatment of humeral fractures in the elderly with an intramedullary nail, leads to good healing and functional results with an acceptable re-operation rate.

Introduction

In the treatment of humeral shaft fractures good results can be achieved with the Sarmiento brace. For the older patient the choice for a brace is not clear-cut. Because of lower bone quality often combined with co-morbidity and as functional demands in these patients are thought to be low, non-operative treatment is often preferred [18, 39]. Older patients however cope less with braces and impaired function of an arm [4, 18, 39]. Obesity, as is often the case in older women, non-compliance due to dementia, and lower muscle tone compromise treatment with brace [27, 37, 49]. Furthermore, with osteoporosis the bone healing process is slower and more susceptible to disturbing factors. Therefore an adequate and stable reduction of the fracture with sufficient bony contact is necessary [5].

Due to improved medical care, the older patient tends to be fit and self-supporting. Improper treatment may lead to functional and social impairment and loss of independency [10, 38, 51]. A stable osteosynthesis allowing immediate full use of the arm may be the better choice [18, 52].

This study was conducted to evaluate the use of a reamed intramedullary locking nail in the treatment of humeral shaft fractures in the elderly, considering healing and longterm functional results.

Patients and method

In a retrospective analysis of prospectively gathered data in a multicentre study in the Netherlands, 113 patients with 114 humeral fractures were included. Of these, 40 patients were 60 years or older and were eligible for inclusion in this study. Five patients were lost early from follow-up: 3 patients had died (1 polytrauma and 2 due to unrelated causes),1 patient with dementia had discharged herself from further follow-up and the fifth went for follow-up in her home region. So, 35 patients could be followed at least till fracture healing. One patient (Table I, nr. 10) could be retrieved for functional assessment which made a total of 36 patients at final follow-up. Missing data were completed by revision of patient files.

All patients were treated with the Telescopic Locking Nail® (TLN®) (Stryker-Trauma, Schönfeld, Germany) [19,20,48]. Nails were introduced retrograde or antegrade depending on the surgeon's preference. The portals for nail introduction are the same as described in the literature: medial from the greater tubercle in case of antegrade nailing and supracondylar in case of retrograde nailing. An example is shown in Figure 1. During regular follow-up functional assessment only had been done by measurement of range of motion (ROM) of shoulder and elbow and was incomplete. We evaluated the long-term functional results in a follow-up study. Patients were invited to the out patient department for functional assessment. The shoulder function was assessed with the Neer score, the elbow function with the Morrey score. To compensate for pre-existing functional impairment because of possible degenerative changes, the relative functional score compared to the contralateral (non-affected) side was calculated.

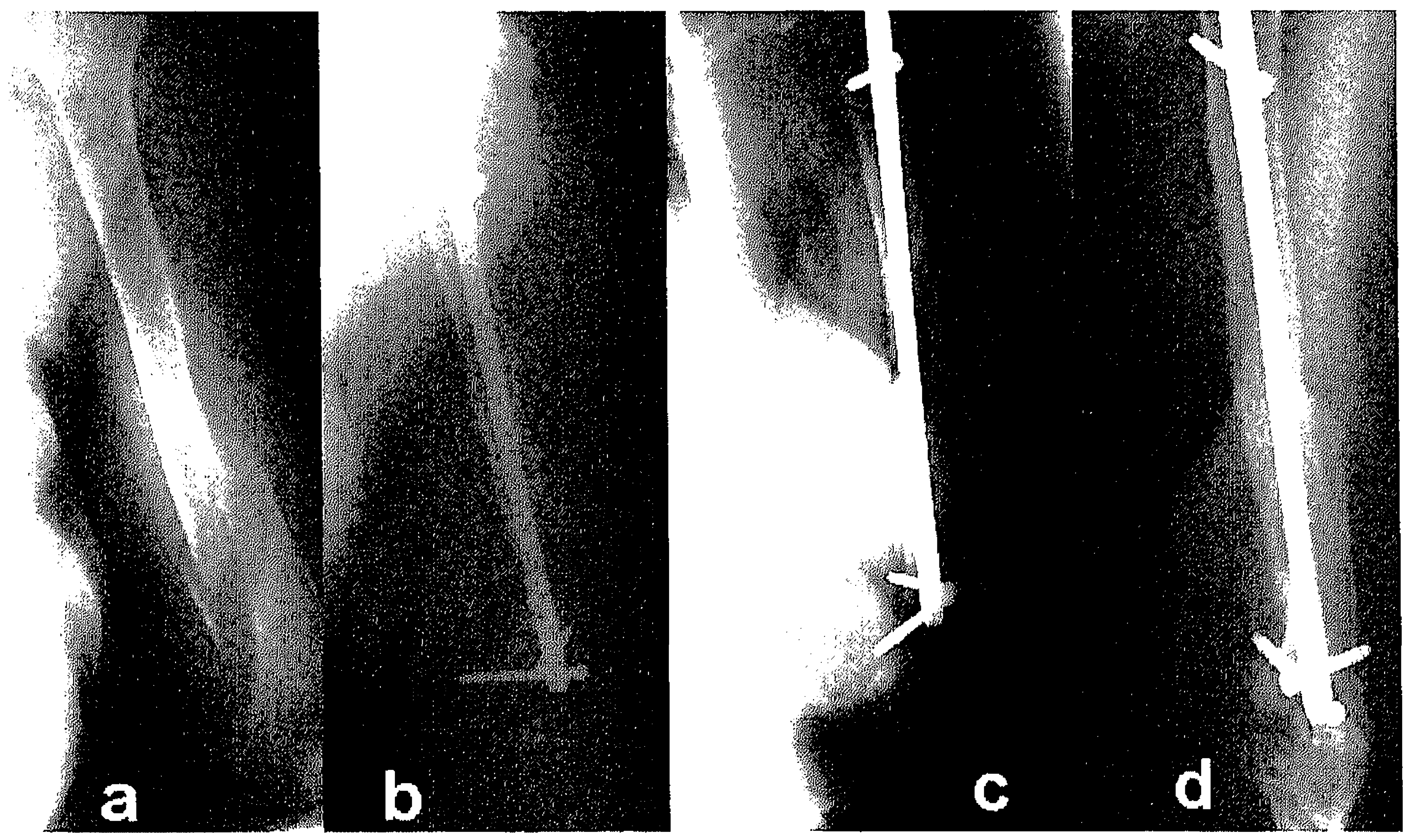

Figure 1: A distal humeral fracture treated with the TLN®: a) fracture, b) after antegrade nailing, c and d) after healing.

Results

There were 36 females and 4 males with a mean age of 75 (range 60 - 87) years. 16 patients were known with one or more comorbidities. These are listed in Table I and Table II. Heart disease (n=8), diabetes (n=3) and dementia (n=5) were the most frequent. 3 patients suffered from more than one disease. All fractures but one were caused by a fall from standing height; one was a polytrauma due to a traffic accident.

The mean follow-up was 14 (range 12-47) months. All fractures were classified according to the AO classification. There were 28 type A, 7 type B and 5 type C. 18 were in the proximal third, 20 midshaft and 2 in the distal third. 21 patients, 2 males and 19 females with a mean age of 77 (range 64-86) years, were stabilized as soon as possible (Table I). The time between trauma and stabilization was a mean of 6 (range 0 - 16) days. 19 patients, 2 males and 17 females with a mean age of 73 (range 60-87) years, were treated primarily in a non-operative way (Table II). The operative stabilization was done after a mean of 28 (range 9-63) days. The reason to switch therapy was in 10 patients a delayed union, in 8 inability to maintain reposition and in one patient wish.

In 24 patients the nail was introduced antegrade and in 16 retrograde. In one patient an iatrogenic fracture occurred with antegrade introduction without any consequences for stability. In two patients an open reposition was necessary because of soft tissue interposition. Two primary radial nerve palsies needed exploration. Of 35 patients, 33 (94%) came to healing in a mean of 17 (range 6-61) weeks. Two patients (6%) developed a non-union. One was not re-operated because of her bad general condition. The other underwent exchange nailing with compression and came to healing eventually. This gives a healing rate of 97% (34/35) after a mean of eighteen (range 6-61) weeks. In three more patients a re-operation was necessary. In one the nail had to be removed after fracture healing because of shoulder impingement, the second had a distal locking screw removed because of pain and in a third patient a locking screw had to be replaced to improve stability. Total re-operation rate was 11% (4/35). One (2.5%) postoperative radial nerve palsy recovered spontaneously. Of two primary radial nerve lesions only one recovered completely. We encountered one superficial infection, which responded well to antibiotics. In one demented patient the nail broke out after a fall. This was treated with a brace followed by an uneventful healing.

After a mean of 3.8 (range 1.9-5.6) years 18 patients out of 36 (50 %) could be contacted and/or were willing to come to the outpatient department. The median Neer score was 90 (range 45 - 97) points and the median Morrey score 98 (range 74-100) points. These are considered "excellent" in the respective scores. We compared the retrograde treated fractures with the antegrade and the primary treated with the secondary treated. Functional results were comparable in all subgroups with for the Neer score a median of 89 (range 54-94) points and for the Morrey score 93 (range 74-100) in the antegrade group, 91 (range 45-97) and 98 (range 94-100) points respectively in the retrograde group, 90 (range 70-94) resp. 100 (range 75-100) points in the primary operated and 89 (range 45-97) and 96 (range 74-100) points in the secondary operated. The median relative score for shoulder was 94 (range 56-101) points and for the elbow 100 (range 98-100) points (Figure 2). Because only 18 patients were available for final follow-up we reviewed the function assessed by ROM at fracture healing to preclude having lost patients with specific very good or very bad functional results. Five patients had not been scored properly and their function was rated only as "limited". For 2 patients no functional assessment had been reported at all. Shoulder elevation, elbow extension and flexion had been recorded properly in 11 patients out of 18 (61%) missing at final follow-up. They had a median shoulder elevation of 180° (range 90°-180°), a median elbow extension of 0° (range 0°-45°). Elbow flexion was recorded as "unaffected" when flexion was more then 120°. This was the case in all 11 patients. Combining the ROM at final follow-up and at fracture healing we found for 29 out of 36 patients (81%) a median shoulder elevation of 145° (range 80°-180°), a median elbow extension of 0° (range 0°-30°) and elbow flexion of at least 130° in all cases.

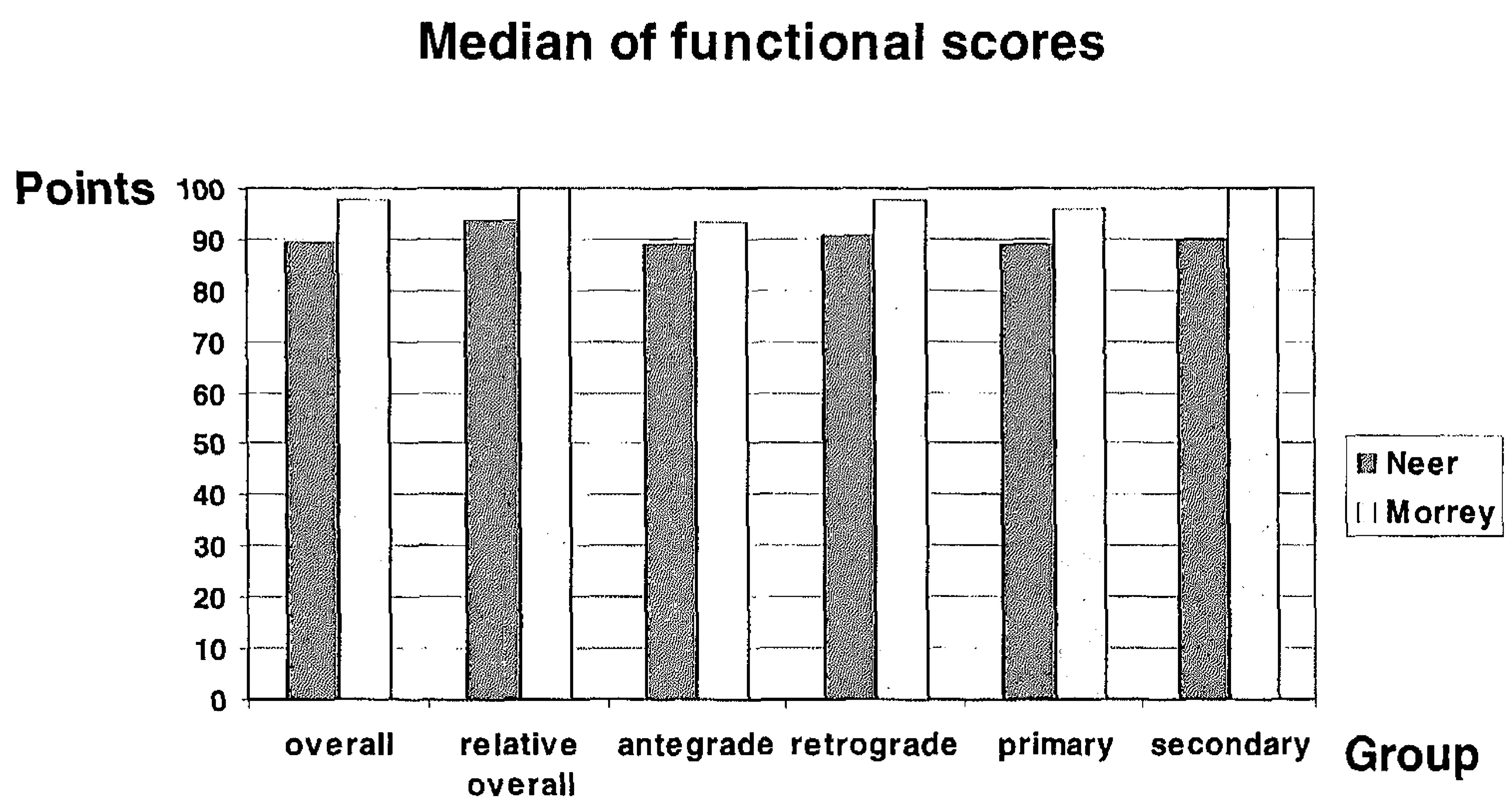

Figure2: Functional results of 18 out of 35 patients according to the treatment modalities.

Table I: Patients treated primarily with an intramedullary nail

Pat.	sex	Age	Delay (days)	Fracture type (AO/ASIF)	Fracture level	Introduction	Complications	Healing (weeks)	NEER	MORREY	Shoulder elevation (°)	Elbow flexion (°)	Elbow extension (°)	Comorbidities
1	f	77	1	A	mid	retro		16	-	-	180	>120	0	
2	f	75	2	A	dist	ante		24	-	-	80	>120	0	cardiac disease
3	f	72	2	A	prox	retro		17	91	100	120	>120	0	cardiac disease diabetes
4	m	82	15	A	prox	ante		14	-	-	180	>120	0	renal disease
5	f	64	11	A	mid	ante		18	91	100	160	>120	0	
6	f	81	0	B	mid	retro		11	-	-	---------	"limited"	---------	cardiac, lung, dementia rheumatic
7	f	82	15	B	prox	ante		18			90	>120	10	
8	f	77	14	A	mid	ante		13	70	75	80	>120	15	Parkinson
9	f	81	0	A	prox	retro		20	-	-	---------	"limited"	---------	dementia, dystrophia myotonica
10	f	79	3	A	mid	retro		lost (could be included at final FU)	86	95	130	>120	10	
11	f	84	2	B	mid	retro	infection	lost	-	-	-	-	-	pseudomyxoma peritonei
12	f	73	6	A	mid	ante		lost	-	-	-	-	-	
13	f	81	1	A	prox	ante		6	-	-	180	>120	0	
14	f	85	7	A	mid	retro		28	-	-	?	?	?	
15	f	74	11	A	mid	ante		8	94	100	180	>120	10	
16	f	71	16	A	prox	ante		6			180	>120	0	
17	f	86	0	A	mid	ante		6	78	99	90	>120	10	
18	m	70	1	A	mid	ante		9	90	100	180	>120	0	
19	f	74	4	A	prox	ante		lost	-	-	-	-	-	
20	f	64	10	A	prox	retro		12	-	-	?	?	?	cardiac disease
21	f	85	0	C	prox	retro	primary radial palsy	61	-	-	---------	"limited"	---------	dementia

Table II: Patients treated secundarily with a nail after first intention of non-operative treatment

Pat.	Sex	Age	Delay (days)	Reason to switch	Fracture type (AO/ASIF)	Fracture level	Introduction	Complication	Healing (weeks)	NEER	MORREY	Shoulder elevation (°)	Elbow flexion (°)	Elbow extension (°)	Comorbidity
1	m	61	50	del union	A	mid	ante		15	91	95	145	>120	0	
2	f	74	9	dislocation	A	prox	ante		12	90	100	145	>120	0	
3	f	85	25	del union	A	mid	ante		16	-	-	110	>120	20	diabetes
4	f	71	25	dislocation	B	mid	ante	iatrog.fracture	12	64	94	140	>120	0	cardiac disease
5	f	64	20	dislocation	A	prox	retro		20	97	100	180	>120	0	
6	f	74	28	del union	B	dist	ante	non-union (healed after re-operation)	51	54	92	80	>120	10	homarthrosis
7	f	79	13	del union	C	prox	ante		12	-	-	180	>120	0	
8	f	62	29	dislocation	C	prox	ante		12	60	74	130	>120	0	diabetes
9	f	66	63	del union	A	prox	retro		8	92	98	165	>120	0	
10	f	60	46	del union	B	mid	ante	primary radial palsy	33	-	-	180	>120	0	
11	f	77	40	del union	A	mid	retro		12	93	100	155	>120	10	cardiac disease
12	f	60	23	del union	A	mid	retro		34	60	96	100	>120	0	
13	f	74	32	dislocation	A	prox	ante		20	89	98	140	>120	10	
14	f	77	10	pat. wish	A	mid	ante		13	-	-	120	>120	10	
15	f	86	17	dislocation	B	mid	retro	secundary radial palsy	18	-	-	180	>120	0	cardiac disease
16	m	80	22	dislocation	A	prox	ante		lost	-	-	-	-	-	
17	f	87	26	dislocation	C	mid	retro		16	-	-		------------"limited"------------		cardiac disease
18	f	78	37	del union	A	prox	ante		21	-	-		------------"limited"------------		dementia
19	f	73	19	del union	C	prox	retro	non-union	non-union	45	94	90	>120	30	

Discussion

Specific literature on humeral shaft fractures in the elderly is scarce. No randomised studies exist. Franck et al. reported on the Fixion-Nail® used in 25 humeral fractures in older patients. He had 100% healing with no re-interventions and good functional results after a mean of six months [18]. Ring et al. reported on functional outcome of operative treatment of humeral non-unions in the elderly and later on humeral delayed and non-unions treated with Locking Compression Plates® [38, 39].

Plate osteosynthesis of humeral fractures leads to good healing and functional results [1, 22, 35, 42, 47]. Disadvantages are the large incisions with higher risk of infection and radial nerve palsy. Moreover, osteoporotic bone provides less grip for screws, leading to loosening of the plate [6, 38, 39, 45, 50]. Longer plates with more screws enhance stability but larger incisions compromise soft tissues and periosteum even more. The recently developed locking plate techniques are a solution to this problem [18, 38, 39, 45].

Intramedullary techniques have shorter operation times with less soft tissue damage and blood loss [6, 8, 9, 30]. With elastic nails early functional treatment is not always allowed because of less rotational and axial stability [6, 8, 9, 14, 15, 29, 40, 51, 52]. Especially in the elderly, the wide medullary canal and osteoporosis lead to less stability of the elastic nails [37]. Nail migration up to 29% and distraction of fractures up to 41% have been reported [9, 14]. A locked intramedullary nail is axially and rotationally stable. It does not depend on the holding power of the locking screws in bone to maintain reposition as a plate does. Even if locking screws loosen, fracture stability can be maintained sufficiently by the nail due to nail-bone interference [30, 45]. Iatrogenic fractures and shoulder function impairment with antegrade nailing are the main disadvantages [6, 7, 52].

In prospective randomised studies on treatment of humeral fractures results are not consistent. McCormack et al. concluded that plating is better than nailing because of lower re-operation rates. Healing and functional results were comparable [33]. Chapman et al. found disturbed shoulder function with antegrade nailing and disturbed elbow function with plating. Healing and complication rates were comparable [7]. Meekers et al. found higher non-union and re-operation rates with the nail in a retrospective comparative study [34]. Lin et al found higher non-union rates with the plate and better function with the nail [30].

We used a reamed locking nail for the treatment of humeral shaft fractures in 40 older patients. Nail introduction in the humerus is still a matter of discussion. In our view distal 3rd fractures should be approached from proximal and vice versa. Nailing from the longer into the smaller fragment is technically easier and there is no risk of destabilising the smaller fragment through an iatrogenic fracture, compromising the whole osteosynthesis [3, 21, 50]. On the other hand nail introduction from the smaller into the larger fragment is biomechanically more stable [31]. In case of midshaft fracture both options are open but we prefer retrograde nailing to stay extra-articular. In this series 11 midshaft fractures were nailed from proximal versus 9 from distal. This being a multicentre study involving different surgeons each with their personal preferences for nail introduction following the philosophies mentioned above, is the main cause of different techniques applied. Healing and complication rates in this series are comparable with other publications [12, 13, 17, 24, 25, 26, 32, 41, 43]. Non-union occurred in 6% (2/35) of patients. Old age and antegrade nailing have been mentioned as cause of non-union [11, 17, 23]. We did not find such a correlation. Both non-unions occurred in cases where nails were introduced distant from the fracture. Lack of stability could be the cause. However, larger series in the literature with systematic antegrade or retrograde nail introduction independent of fracture level do not report more non-unions in fractures distant from introduction site [12, 13, 28, 41, 43]. On the contrary, non-unions have been mentioned in fractures located midshaft and/or close to introduction site [2, 36, 46].

A re-operation rate of 14% is in line with the 5 up to 45% found in the literature [17, 24, 25, 34, 41, 43, 44]. Two re-operations were necessary to ensure fracture healing: one re-osteosynthsis because of non-union and one bolt replacement to enhance stability. The other re-interventions were in one case nail removal because of protrusion due to insufficient primary technique, and bolt removal because of pain. The latter is a typical problem in humeral nailing caused by prominent bolts [12, 24]. Antegrade nail introduction without reaming caused in one (2.5%) patient an iatrogenic fracture in the distal part. Retrograde introduction caused no iatrogenic fractures in contrast to what one would expect in osteopenic bone. Possibly, the wider medullary canal in the elderly leads to less stress in the cortex during nail introduction.

As only 18 patients could be retrieved for functional assessment, functional results should be interpreted with caution. In view of the mean age of these patients however and because the follow-up study was conducted after 3.8 (range 1.9 -5.6) years, it is to be expected that patients are lost because of death or admittance to a nursing home or that they are reluctant to another hospital visit. Three of the five patients with complications could be included: the two patients with non-unions and the patient with bolt removal. The functional assessement of shoulder and elbow function by ROM however indicates that functional results are generally good and that the 18 patients at final follow-up are representative for the whole study population.

Antegrade nailing is believed to impair shoulder function especially in older patients [17, 23, 41, 43]. We did not find differences in function either between retrograde and antegrade introduction or between early and late operation. In a series with a mean follow-up of 5.5 years Flinkkillä et al. concluded that on the long term antegrade nailing does not lead to clinically relevant disturbance of shoulder function [16]. As reported in the literature, influence on elbow function is minimal even in case of retrograde nailing [32, 41, 43, 44, 48]. Both Neer and Morrey scores are considered "good to excellent" in all subgroups.

This study has the shortcomings of every retrospective study. There is no control group and a substantial part of patients were lost to follow-up. Patients included, were part of a multicentre study on the TLN®. We do not know how many older patients with humeral fractures were treated and which other techniques were used in the institutions involved. Operation indication and technique were left to the preference of the different surgeons. Due to lack of specific literature on this subject however, this study provides us with some arguments in favour of reamed nailing of humeral fractures in the elderly. Good healing and acceptable re-operation rates and good long-term functional results can be achieved. However, in the view of the shortcomings of this study, further prospective studies are necessary to make definite statements.

Conflict of interest statement

A possible conflict of interest exists in the fact that the senior author (J. Stapert) has developed the Telescopic Locking Nail® (TLN®) used in this study together with Howmedica® (now Stryker Trauma®). However there never has been any interference from the senior author nor the company in the interpretation or publication of data. Furthermore, for the moment this implant is no longer available on the market.

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CHAPTER VIII

Failure of reamed nailing in humeral non-union
An analysis of twenty-six patients

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Summary

The use of an intramedullary nail in the treatment of humeral non-unions remains controversial. This study evaluated the treatment of humeral delayed and non-unions with reamed nailing and compression. In a retrospective analysis of prospectively gathered data from 26 cases all treated with the Telescopic Locking Nail® (TLN®), the healing rate after the first intervention for non-union was 58%. After one or more re-interventions combined with an external cancellous bone graft at some time during follow-up, 90% of the 21 patients with complete follow-up eventually healed after a mean of 22 months. A total of 49 procedures with a mean of 1.9 per patient were needed.

After a mean follow-up of 65 (range 24-88) months, we conducted a study to assess the functional results in the shoulder and elbow. Twelve patients were suitable for inclusion. We used the Neer and Morrey score for shoulder and elbow function, respectively. For the Neer score the median was 91 points and for the Morrey score 94 points.

The outcome suggests that simple reamed nailing of humeral non-union is insufficient. Reamed interlocked nailing is feasible, provided that the primary intervention for non-union is combined with an external cancellous bone graft.

Introduction

The occurrence of humeral non-union is up to 8% for non-operative and up to 15% for operative treatment.[16, 20 and 24] Failure rates of 39% in non-operative and 29% in operative treatments have been reported.[16, 21] Humeral non-union is considered an absolute indication for operation. Good healing is described with plate osteosynthesis, with healing rates between 92% and 100%.[2, 4, 12, 20, 32, 33, 44 and 48] This technique is still considered the 'gold standard'. Specific descriptions of the use of intramedullary locking nails in humeral non-union are rare. Most such studies have concerned mixed groups of patients with fresh fractures, non-unions and pathological fractures. The overall results for healing are good, but little attention has been paid to the non-union. In subgroups of three-nine patients with non-union healing rates have varied between 17% and 100%.[1, 8, 13, 21, 22, 29, 31, 43, 50] In specific series of locked nailing for humeral non-union, the healing rate varied between 62% and 98%, depending on the implant and technique used.[10, 30, 46] In the treatment of humeral non-union a stable implant is needed. In order to avoid the possible complications of plating, such as radial nerve damage, extensive dissection and infection, we prefer a minimal invasive procedure with an interlocking nail. A reamed interlocking nail is preferred for maximal rotational and bending stability. An additional advantage of a reamed nail is the reaming debris which provides an internal cancellous bone graft.

This study was conducted to evaluate the treatment of humeral non-union with an internal cancellous bone graft using power reaming of the shaft followed by a stable osteosynthesis with the Telescopic Locking Nail® (TLN®).[19, 49]

Patients and methods

In this retrospective analysis of prospectively gathered data, 26 humeral non- and delayed unions were included. Missing data were completed by reviewing the patient's files. In all patients the TLN® was used. This is a straight nail with a central diameter of 7.6 mm which widens at both ends to 9 mm to allow strong 4.6 mm locking bolts. The technique involved, is reduction of the non-union (closed if possible), followed by power reaming of the shaft. After introducing of the nail and interlocking, compression is applied with the axial compression screw. In cases previously treated with a nail, exchange nailing with reaming of the medullary canal was performed. Antegrade and retrograde introduction are possible but we prefer an extra-articular procedure with retrograde nailing. The nails were introduced retrograde in 17 of the patients and antegrade in 9. An example is shown in Figure 1.

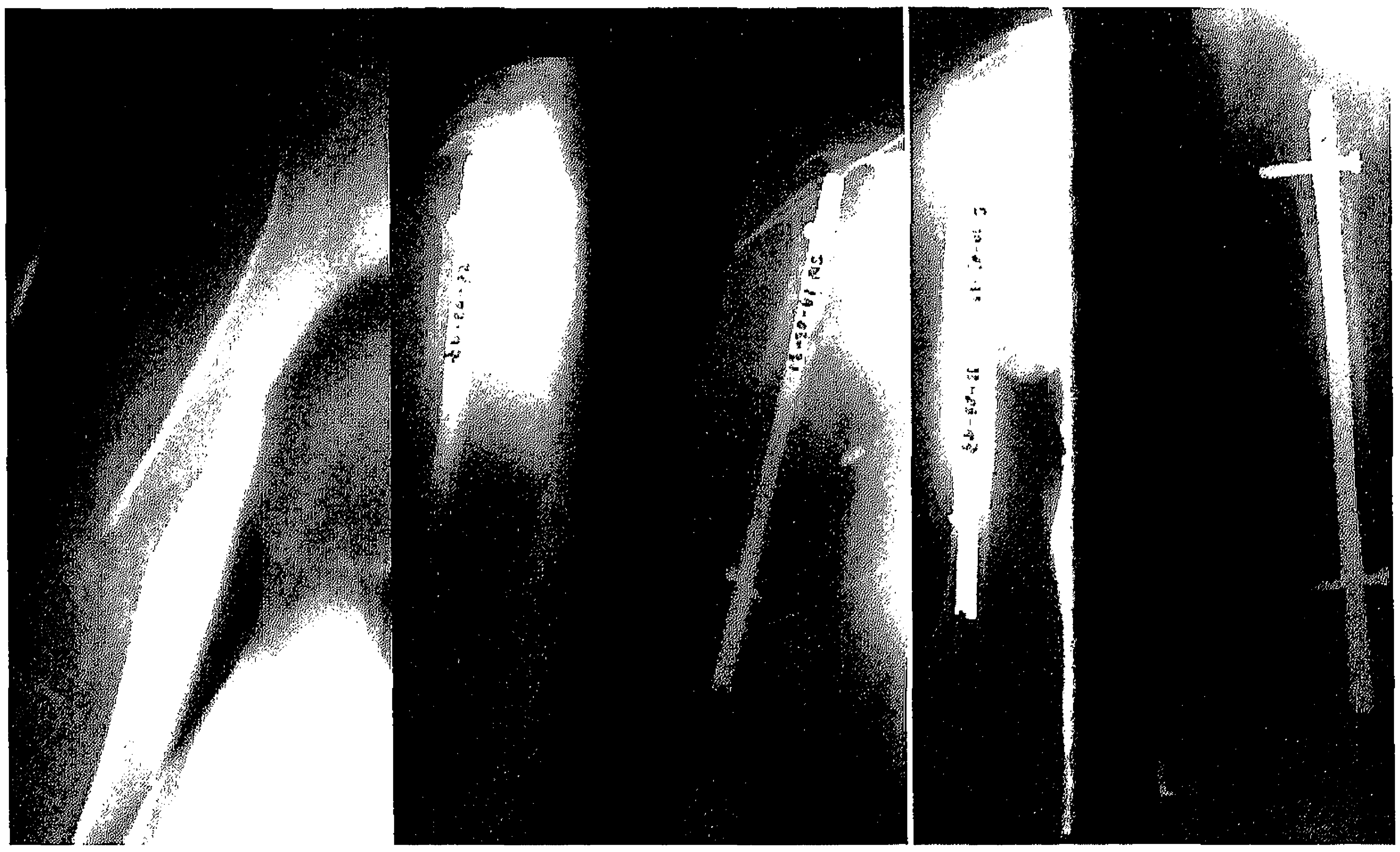

Figure 1. Left: fracture of the proximal humeral shaft without signs of callus formation. Centre: treatment with retrograde insertion of the TLN®. Right: consolidation of the non-union.

The primary fractures were classified according to the AO/ASIF. We found nine type A1, six type A3, nine type B1, one type C1 and one type C3. Percentages are shown in Figure 2. The fracture level was in the proximal third in 10 cases, in the middle third in 13 cases and in the distal third in three (Figure 3). In 17 cases the primary therapy was conservative. In nine patients the primary therapy had been operative: the techniques used were elastic nails, a TLN® and a plate in two cases each, and an Unreamed Humeral Nail®, a Seidel Humeral Locking Nail® and an external fixator in one case each. One patient with a delayed union had already been treated with elastic nails without success. If no signs of callus formation were seen after 6-8 weeks the fracture was considered a delayed union, after 12 weeks we considered it a non-union. Three delayed unions were included. There were only four hyper- and one oligotrophic non-unions. In 18 cases the non-union was hypotrophic. Two patients withdrew from further therapy, but one of them could be retrieved for functional evaluation. Two geriatric patients and one patient with cancer had been discharged from further therapy despite a persistent non-union after nailing with the TLN®. They died without assessment of healing. Twenty-one patients had complete follow-up. After a mean follow-up of 65 (range 24-88) months, we conducted a study to evaluate the functional results. Twelve patients were suitable for inclusion. Shoulder and elbow function were assessed with the Neer and Morrey score, respectively.

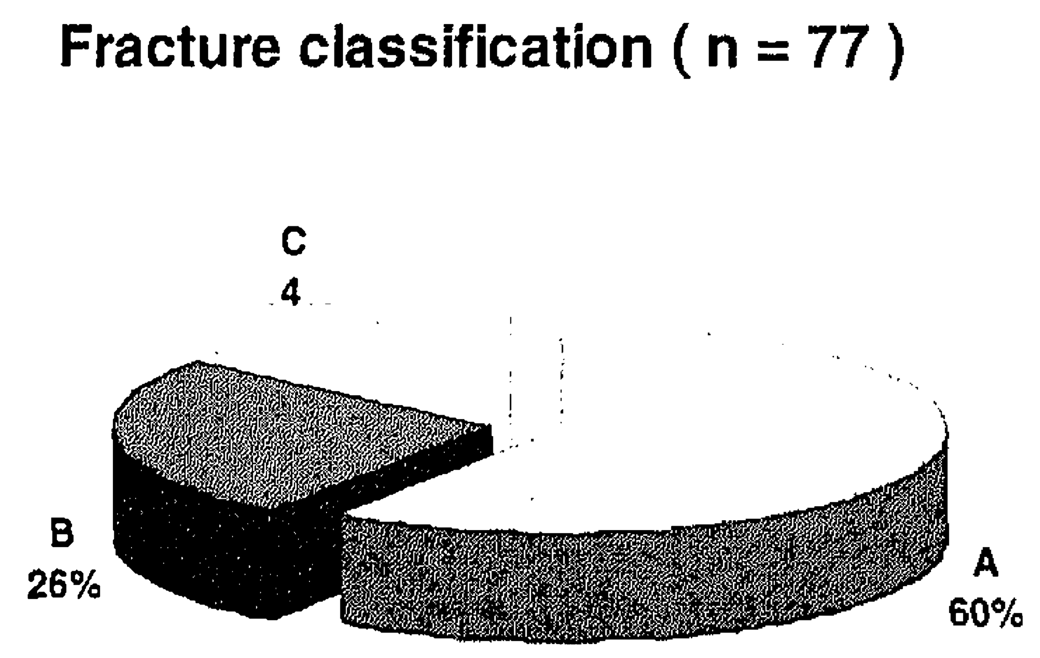

Figure 2: Fracture classification according to the AO of the 77 fractures

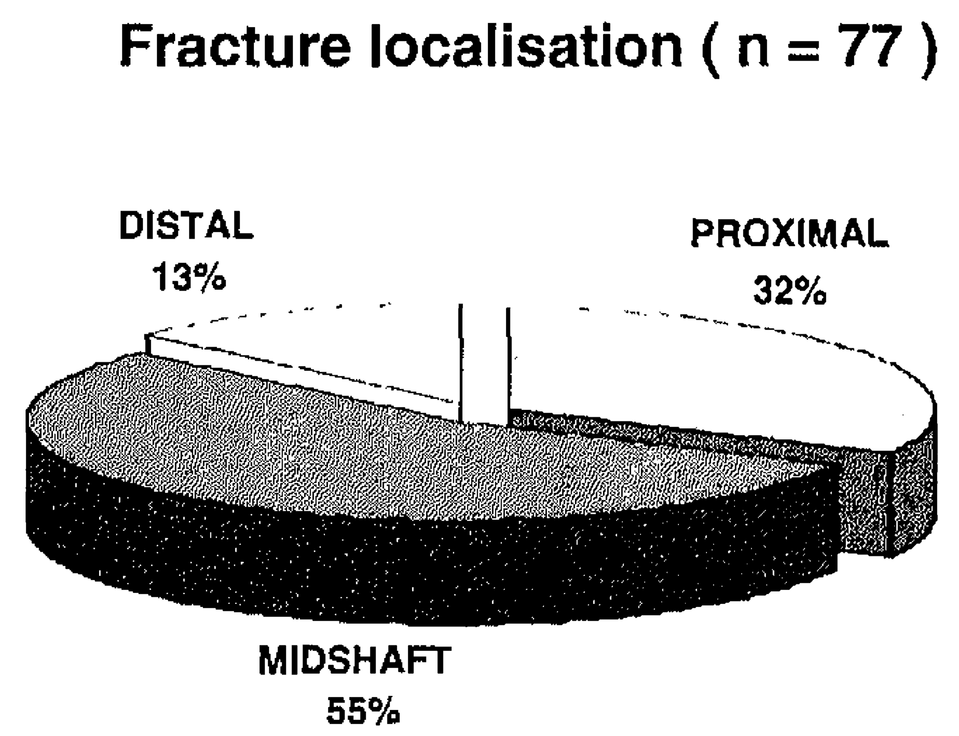

Figure 3: Localization of fractures of 77 fractures of the humeral shaft

Results

There were 15 females and 11 males with a mean age of 57 years (range 19-86 years). The mean interval between trauma and first treatment for non-union was 48 weeks (range 7-467 weeks). Healing was achieved after a mean of 22 months (range 5-55 months) in 19 of the patients (n = 21). Fifteen non-unions healed after the first intervention with the TLN®, eight needed two and three needed three procedures. A total of 49 procedures, including the interventions before the introduction of the TLN®, was needed, with a mean of 1.9 (range 1-4) operations per patient. Among these were three re-interventions for deep infection, treated by nail removal, reaming and antibiotic beads. Temporary stabilisation was provided with a brace in one case and in an other with an external fixator. The third case appeared to be healed. After the infection subsided, re-osteosynthesis was performed in the two remaining cases, one with a TLN® and the other with a plate. Both healed uneventfully.

In three cases, stability needed to be improved by the introduction of new locking bolts (n = 2) and an encircling wire loop (n = 1). In eight patients there was a primary neural lesion. Two patients had a plexus lesion. In one case a radial nerve palsy after prior plate osteosynthesis had not resolved and a tendon transposition was performed. In five patients, the primary radial palsy had resolved spontaneously. One radial nerve palsy appeared postoperatively, but also resolved spontaneously. In four patients an iatrogenic fracture occurred with retrograde introduction of the nail. Two needed stabilisation: one with screws and the other with an encircling wire loop.

Of the 49 procedures needed to achieve healing, 33 were intramedullary osteosyntheses. Eleven of these were exchange nailings. In all cases that needed more than one procedure, healing occurred after an external cancellous bone graft. Two patients underwent electromagnetic bone stimulation some time during their treatment, without success.

After a mean follow-up of 65 months (range 24-88 months), 12 patients could be re-evaluated for shoulder and elbow function. Their mean Neer score was 78 points (range 43-99 points); their mean Morrey score was 89 points (range 40-100 points); These scores are considered unsatisfactory and good, respectively. As one patient had a very low score because of a plexus lesion, the median score is a more appropriate variable: this was 91 points for the Neer and 94 points for the Morrey score, excellent and good scores respectively. Seven patients scored excellent on the Neer score; five were failures. For the elbow, six patients scored excellent, three good, two fair and one poor. Patient's details are presented in Table I.

Discussion

The main causes of humeral non-union are instability over the fracture, insufficient bony contact and loss of blood supply. Transverse and short oblique fractures, comminuted fractures and open fractures are particularly predisposed to non-union. In operatively treated humeral fractures, inadequate technique and extensive debridement are causes of non-union. Patient-related factors are compliance, obesity, alcohol abuse, smoking and multiple fractures.[16, 23, 24 and 44] Cox et al.[7] reported that old age is also a risk factor for the development of humeral non-union.

Our patient group is similar to these in either published studies. The fractures were mostly type A and mid-shaft. The majority of the patients were primarily treated non-operatively. In the operated patients, the stability of the implants was insufficient. In one patient alcohol abuse and in another obesity were contributing factors. In three patients a delayed union was diagnosed after 7-9 weeks. Consensus exists that, if a humeral fracture treated non-operatively shows no callus formation after 6-8 weeks, healing will be very unlikely to occur and stabilisation is mandatory.[4, 16, 24 and 35] If a fracture is not healed after 12-16 weeks it is considered a non-union.[16] In general non-unions are divided in to hypertrophic and atrophic. Hypertrophic non-unions mostly require only biomechanical stabilisation to come to healing, whereas atrophic types should always be treated in combination with a cancellous bone graft. In our series we had four hypertrophic non-unions. One became infected and healed after repetitive debridement and nailing after the infection had subsided; the other two needed two nailing procedures before healing.

A primary healing rate of 58% after reaming and a stable osteosynthesis with a TLN® was an unexpected result. The technique used (anatomical reduction, power reaming and stable fixation with a nail) is in keeping with the principles of treatment of non-unions. The reaming provides the necessary bone graft.[17, 18] The TLN® with compression guarantees stable fixation with its strong locking bolts and compression. A total of 49 procedures (mean of 1.9) were needed for eventual healing in 19 of 21 cases. All such healing occurred after an external cancellous bone graft. In a comparable series of 26 patients treated with plating in combination with cancellous bone graft, there was a healing rate of 92% after a total of 46 procedures (mean 1.8 per patient).[20]

Küntscher has introduced reamed nailing of humeral non-unions; reaming was necessary to allow thick intramedullary nails be impinged with a maximum of bony contact.[26] Christensen[5] described primary healing in seven out of 13 patients with this technique; three more healed only after a second operation; failure was ascribed to a lack of rotational stability. Compression plating with or without a cancellous bone graft achieved better results. Fattah et al. concluded that, although Küntscher nailing of humeral non-union in his series led to 100% healing, nailing was inferior to the compression plate because of the longer healing time and limitation of function[12]. Despite the extensive dissection, the higher infection rate and the risk of radial nerve damage in plating, it still remains the technique of choice. Healing rates between 94% and 100% were reported in early studies[4, 12, 32] these results were confirmed in later studies, with healing rates between 92% and 100%.[2, 20, 33, 44, 48]

With the introduction of interlocked nails for the humerus, extensive reaming was no longer necessary; rotational stability was achieved by interlocking the nail. Since then, different types of nails have been used in the treatment of humeral non-unions with varying results. Most studies have concerned mixed patient groups treated with an intramedullary nail for acute fractures, non-union and (impending) pathological fractures, with healing rates for the non-unions ranging from 17% to 100%.[1, 8, 21, 22, 31, 43, 47] Specific studies on the treatment of humeral non-union with interlocking nails are rare. Schwarz and Posh[46] reported healing of five out of eight (62.5%); Dujardin et al.[10] had a healing in eight out of 13 (62%). Linn et al.[30] suggest the use of double transfixing interlocked nails and compression by back lashing, in his series of 41 cases, they achieved a healing rate of 98%, all but two patients received an open cancellous bone graft, losing the advantage of a minimal invasive technique. No prospective randomised studies have been published, but there have been some retrospective comparative studies. Foster et al.[15] found a healing rate of 80% with plate osteosynthesis compared to 73% with Küntscher nailing. Wu and Shih[51] found similar healing rates of 89.5% and 87.5% for plate and nail, respectively, but the nail had fewer complications and a shorter operation time. An overview of the various publications is given in Table II. Eleven nailing procedures in our series were exchanges. In contrast to the good results achieved with exchange nailing in the treatment of femoral and tibial non-union,[6] this technique is not as successful in humeral non-union. Robinson et al.[42] was only successful in two out of five, Flinkkilä et al.[14] in six out of 13, and McKee et al.[35] in six out of 10. McKee concluded that compared to the plate, locking nails were not suitable for the treatment of humeral non-unions. Most investigators have used various nails in the same study, among these Humeral Locking Nails® and Russell-Taylor Nails®. These nails are rotationally unstable both clinically and biomechanically and therefore less suitable for the treatment of humeral non-union,[9, 11, 45] due to the lack of axial compression. The humerus is subjected much more to rotational and distraction forces whereas in the lower extremity compression forces predominate.[2, 27, 36, 38] Court-Brown et al.,[6] however, attributed the success of exchange nailing in the tibia to the increase of periosteal blood flow. The question remains why this does not work for the humerus. Flinkkilä et al.[14] found that reaming of the shaft did not result in periosteal callus formation, as one would expect with an increased periosteal blood flow. The technique of repetitive compression with the Ilizarov external fixator might be an answer to this problem.[27, 38, 40]

Compression increases the stability of the osteosynthesis. If a fracture is protected from all forces except compression, it will heal eventually.[24, 39] In the treatment of humeral non-union with plates, compression is the standard.[4, 32] The implant we used is an interlocking compression nail; an axial screw exerts the compression. Theoretically, our treatment concept allows a completely closed procedure, but the healing results refute this.

According to Dujardin et al.[10] the only factors contributing to healing of humeral non-union are the condition of local soft and bony tissues and the stability of the osteosynthesis. As a stable osteosynthesis with compression nailing, but without an external bone graft did not have the expected results in our series, local conditions are probably more important. Despite the internal bone graft, no healing occurred after the first intervention with the TLN®. It is very likely that, in contrast with fresh fractures, power reaming does not generate enough cancellous bone to be extruded through the fracture fragments due to existing fibrosis over the fracture gap.[6] Debridement of fibrous tissue and decortication might be important to stimulate revascularisation. Martinez et al.[34] used the Vincenzi-Marchetti-Nail®, a rotational, less stable implant; with open debridement and a cancellous bone graft they achieved a 100% healing rate. Lavini et al.[28] had similar results with open debridement and a cancellous bone graft in combination with an external fixator. This suggests that excessive debridement and a bone graft are of prime importance in the treatment of humeral non-union. The non-unions in our series that needed more than one procedure all healed after an external cancellous bone graft. In one case, healing occurred only after a plate osteosynthesis combined with a cancellous bone graft.

Our results and those published before suggest that the problems of healing in humeral non-union are primarily caused by lack of 'biology' not lack of stability.

Debridement and cancellous bone grafting almost always results in healing regardless of the technique used. The work of Brownlow and Reed [3, 41] demonstrated that even atrophic non-unions are not avascular, suggesting that stimulation of bone healing should be looked for in the treatment of humeral non-union. Kloen et al. demonstrated that in non-unions, bone morphogenetic proteins (BMP) are present and active; they could not show a difference in expression of BMPs in humeral non-unions compared to other bones.[25] The failure of reamed nailing in our series might be due to destruction of the vascular structures in the non-union site by power reaming. Anatomical studies of humeral vascularisation demonstrate that the endosteal vessels provide the main part of the blood supply in the humeral shaft.[37]

Aside from union and anatomical correction, another goal of the treatment of humeral non-unions is the free and painless use of the extremity. The functional results in our series are good. A median of 91 and 94 points for the Neer and Morrey score, respectively, is considered excellent and good. This observation underlines the importance of an osteosynthesis allowing early functional treatment, especially with non-unions. Furthermore, as antegrade nailing may impair shoulder function, we recommend retrograde introduction whenever possible. Especially with exchange nailing in the antegrade way (further) damage to the rotator cuff is very likely.[36, 46] Comparison with other series is difficult because different investigators use different evaluation methods and eventual healing is considered more important.

The treatment of humeral non-union remains a challenge for the surgeon. To come to uneventful healing, one should stick to the general principles. The plate osteosynthesis remains the treatment of choice. Our treatment concept of simple intramedullary nailing with reaming and compression is obviously not sufficient in the treatment of humeral non-union. Also, exchange nailing, in contrast to its relative efficacy in tibial and femoral non-unions, does not suffice in the humerus even with a stable implant. We can only recommend the use of a reamed intramedullary nail such as the TLN® as an alternative for plate osteosynthesis in combination with an external cancellous bone graft. However, we agree with Dujardin et al. that instead of abandoning this technique, further research on the reasons for its failure should be conducted [10]. New developments in the molecular biology of bone healing might be an important step in the solution to this problem.

PAT.	AGE	SEX	FRACT. TYPE	NON-UNION TYPE	DELAY (WEEKS)	NUMBER OF PROCEDURES	HEALING TIME (MTHS)	NEER	MORREY
1	21	M	A3.2	delayed union	7	1	5	99	99
2	66	F	A1.1	delayed union	9	1	6	92	98
3	19	M	A3.2	delayed union	10	1	5	98	100
4	86	F	B1.2	hypotrophic	14	1	6	-	-
5	74	F	A1.2	hypotrophic	14	1	8		
6	72	M	C1.2	hypotrophic	15	2	non-union	-	-
7	75	F	A1.2	hypotrophic	15	1	10	90	95
8	50	M	B1.1	hypertrophic	16	2	non-union	-	-
9	74	F	B1.1	hypotrophic	17	2	39	67	93
10	66	F	B1.1	hypotrophic	19	3	42	-	-
11	60	F	C3.2	hypertrophic	21	2	6	-	-
12	79	F	B1.1	hypotrophic	22	1	non-union		
13	68	M	A1.1	hypotrophic	22	3	non-union	-	-
14	45	M	B1.2	hypotrophic	30	2	non-union	94	100
15	84	F	A1.2	hypotrophic	32	2	non-union	-	-
16	34	M	A3.2	hypertrophic	34	4	55	50	70
17	41	M	A3.2	hypotrophic	37	2	22	-	-
18	50	F	A3.2	hypotrophic	38	2	51	-	-
19	42	M	A3,3	oligotrophic	41	2	14	43	40
20	21	M	A1.1	hypotrophic	46	1	15	91	93
21	53	F	B1.1	hypotrophic	47	3	29	-	-
22	83	F	A1.1	hypotrophic	48	2	22	61	87
23	75	F	A1.3	hypertrophic	53	2	37	54	92
24	55	F	A1.2	hypotrophic	77	2	11	-	-
25	44	F	B1.3	hypotrophic	94	2	29	98	100
26	53	M	B1.1	hypotrophic	467	2	non-union	-	-

Table I: Overview of 26 patients with humeral non-union tretaed with a TLN®

F.U. (MTHS)	*COMPLICATIONS*	*REMARKS*
77		
55		
80	Primary radial nerve palsy	
7	Per-operative fracture, fixed	
13	Primary radial nerve palsy / per-operative .fracture	
21		*Deceased*
80	Open procedure	
37		
82	Primary radial nerve palsy	
46	Infection	
8	Primary radial nerve palsy	
9		Lost to F.U.
24		*Shoulder arthrodesis /* prostate ca. / deceased
62	Nail broke out after fall, re-osteosynthesis	Withdrew from further treatment
18	Radial nerve palsy post -op. / per-operative fracture, fixed	Frozen shoulder / deceased
81	*Pre-op. plexus lesion / infection*	Bone stimulation did not work
22		
51		
88	Pre-operative plexus lesion	
85	Primary radial nerve lesion, recovered	
39		
56		
42		*Homarthrosis +++*
29		
28	Infection	Bone stimulation did not work
121		

Table II : Overview of the results of different series presented in the literature.

AUTHOR	IMPLANT	PATIENTS (TOTAL)	NON-UNIONS (n)	UNION	%
Svend-Hansen	Seidel	31	7	3	43
Crolla	Seidel	46	9	6	67
Hems	Russell-Taylor	43	4	2	50
Ajmal	Russell-Taylor	33	6	1	17
Rommens	Russell-Taylor	48	3	1	33
Loitz	UHN®, HVN®	120	5	4	80
Ingman	Modified Grosse-Kempf tibial nail	41	5	4	80
Schwarz	Seidel	14	8	5	63
Flinkkila (1999)	Küntscher, Seidel	126	11	7	64
Dujardin	Seidel, Russell-Taylor, Ace	13	13	8	62
Robinson	Seidel	30	5	2	40
Linn	own nail	41	41	41	100
Flinkkila (2001)	Russell-Taylor	24	13	6	46
McKee	Seidel, Russell-Taylor, Uniflex	21	10	6	60

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CHAPTER IX

Compression locked nailing of the humerus
A biomechanical analysis

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Abstract

Background: In the treatment of humeral fractures reamed nailing and compression are reported to create higher stability. In this cadaver study we compare the Unreamed Humeral Nail® with the (reamed) Telescopic Locking Nail® to find out if any differences exist concerning bending and rotational stability both with and without compression.
Method: Nails were tested in a paired set-up with 8 pairs of fresh frozen cadaveric humeri. The nail-bone constructs were submitted to axial distraction to test compression, four-point bending and torsion. After creating a bone defect simulating an unstable fracture, bending and torsional tests were run again.
Results: After cyclic loading, distraction under compression with the TLN® was significantly less than with the UHN®: 0.10 (SD 0.06) vs. 0.31 (SD 0.18) mm (difference -67%, 95%CI = -84% to -37%; p=0.01). In bending the constructs with TLN® under compression were more stiff than those with the UHN: 0.96 (SD 0.25) vs. 0.80 (SD 0.25) kN/mm (difference = 0.16, 95%CI = 0.07 to 0.25, p=0.01). In torsion and with a bone defect, no significant differences were found.
Conclusion: Both nails are able to resist physiological forces acting on the humerus. The constructs with the TLN® under compression are more stable in bending. Compression with an axial set screw is the more stable option.

Introduction

Due to distracting and rotational forces combined with a smaller bone contact area, transverse and short oblique humeral fractures are susceptible to delayed and non-union [3, 4, 5, 7, 9, 12, 27]. Especially torsional forces are thought to cause non-union of humeral fractures treated with a locking nail [3, 4, 5, 8, 28, 32]. According to the work of Ritter et al. [23, 24] and Mittelmeier et al. [18, 19] on tibial and femoral nails, rotational forces in transverse fractures can only be excluded through interfragmentary compression. In a biomechanical study Blum et al. found a higher bending and torsional stiffness for the Unreamed Humeral Nail® under compression compared to the same nail without compression [4, 5].

The Unreamed Humeral Nail® (UHN®) (Synthes, Betlach-Switserland) and the Telescopic Locking Nail® (TLN®) (Stryker-Trauma, Schönkirchen-Germany) each have a specific compression system. Both implants have been used in clinical practice with good results [2, 5, 10, 25, 30]. In this study we compare both nails concerning their stability against bending and torsion both with and without compression. To our knowledge this is the first study comparing humeral compression nails.

Material and methods

8 pairs of humeri were harvested from 8 fresh frozen human cadavers. To minimize variations in measuring a strictly paired set-up was used to compare both nails. UHN® and TLN® were randomly assigned to left or right humerus of the same individual.

Implants

The UHN® is a solid titanium nail. We used the 7,5 mm version. Compression is given through an external screw which is mounted on the insertion handle. After tightening of this screw, static locking through the aiming device is necessary to maintain compression (Figure 1).

The TLN® is a straight nail of stainless steel. The proximal and distal part of the nail have a diameter of 9 mm to allow the use of strong 4,6 mm lockin bolts. In the central section of the nail the diameter is reduced to 7,6 mm to obtain the necessary elasticity needed for introduction and fracture healing. Compression is applied with an axial set screw (Figure 1).

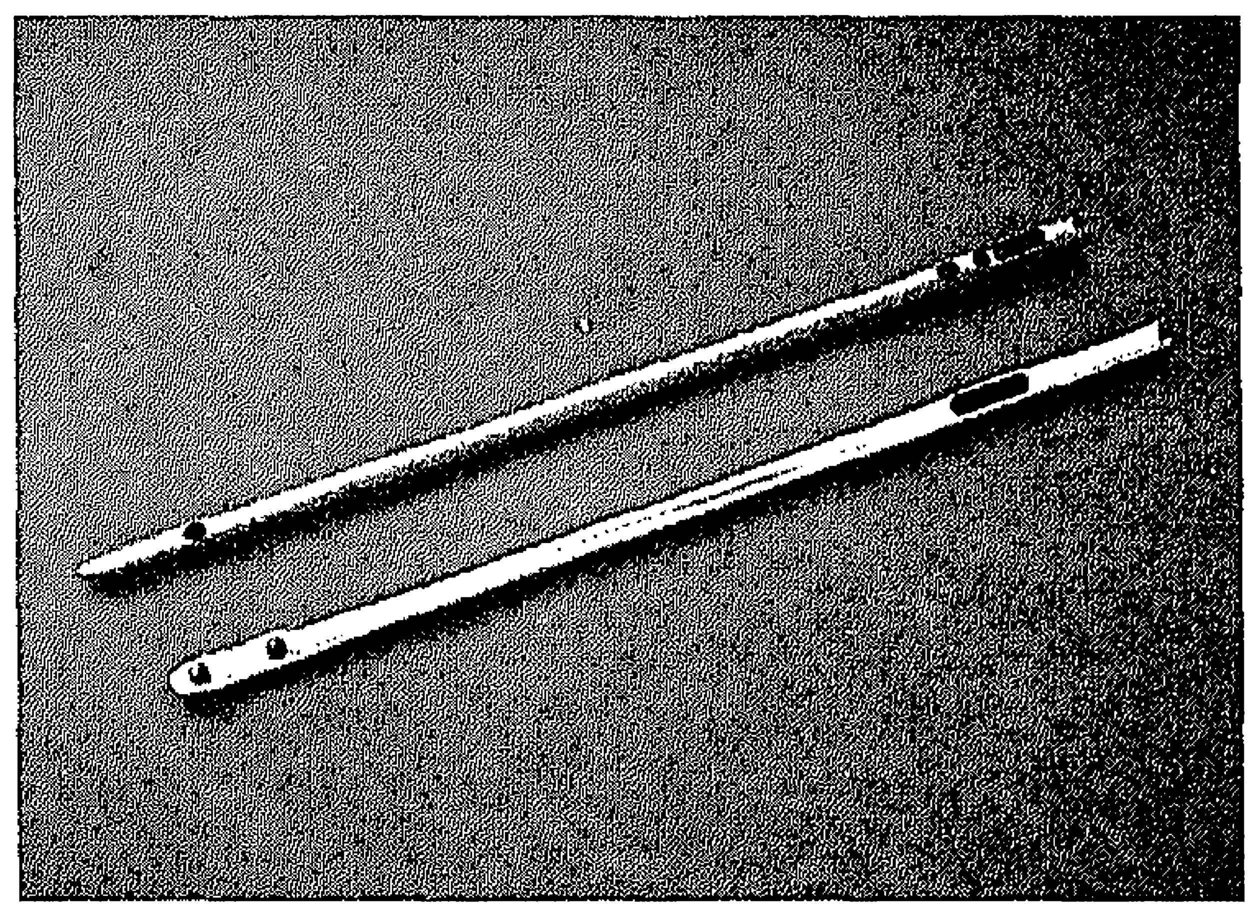

Figure 1: UHN® (left) and TLN® (right).UHN® exists in 6.7, 7.5 and 9.0 mm versions, length varies from 190 mm to 325 mm. TLN® exists in one diameter only, length varies from 185 mm till 310 mm. Locking options are visible.

Specimen preparation

All humeri underwent a DEXA scan to assess Bone Mineral Density (BMD), and radiographical examination to exclude lesions that could influence measurements. Before testing, humeri were thawed overnight at room temperature. Proximal and distal ends were embedded in polymethylmethacrylate (PMMA) (Figure 2). During embedding the introduction site for the nail at the distal end of the humerus was kept free with a piece of foam rubber to allow later introduction of the nails.

After testing of the intact humeri, a midshaft osteotomy was set and the nails were introduced retrograde following the manufacturer's instructions. In the case of the TLN® power reaming to a diameter of 11 mm was used prior to implantation. After interlocking, compression was applied.

After the first tests a circumferential bone defect of 10 mm was created proximal from the original osteotomy (Figure 3). Bending and torsional tests were run again.

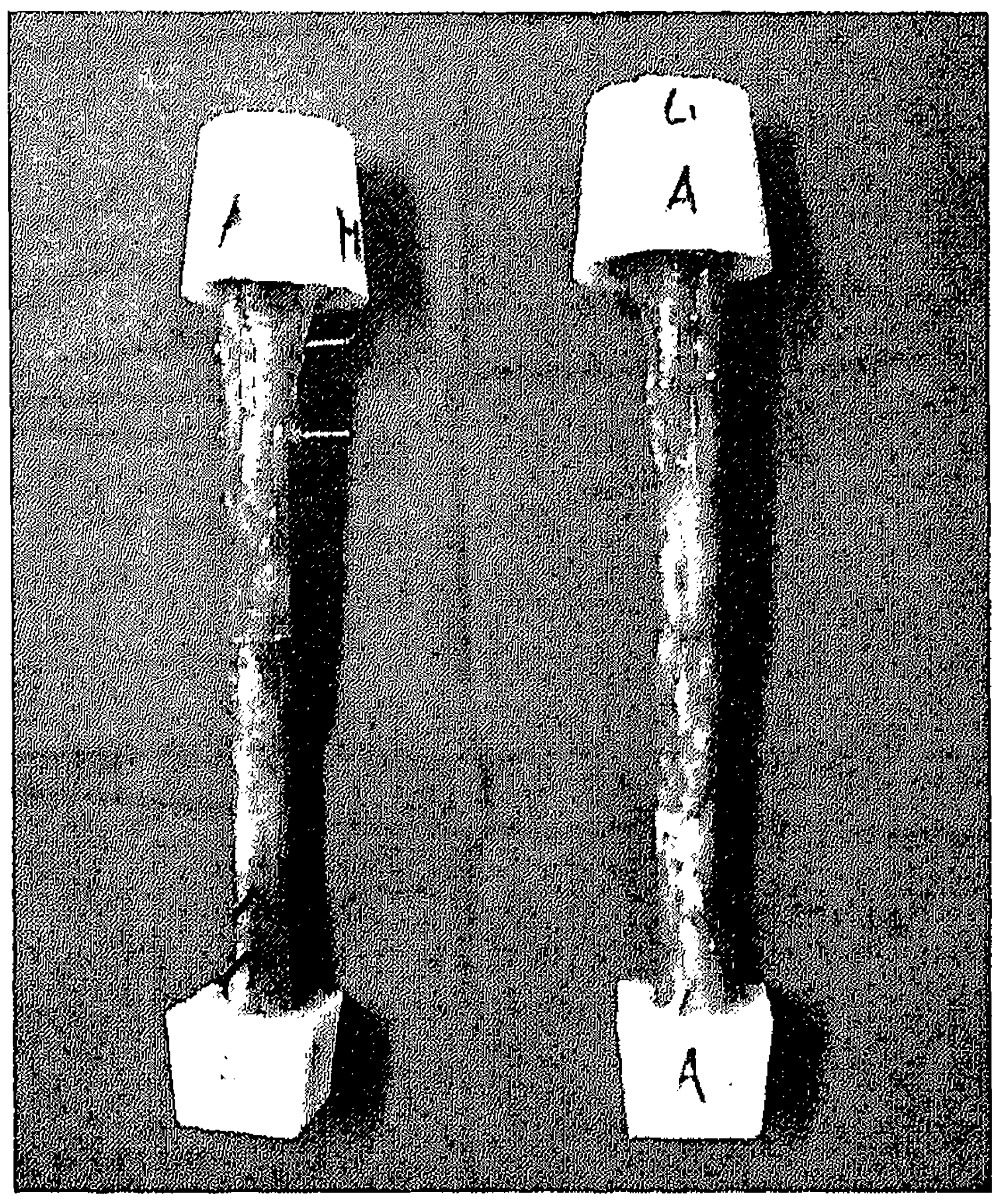

Figure 2: A pair of humeri after embedding in PMMA, osteotomy and implantation of nails.

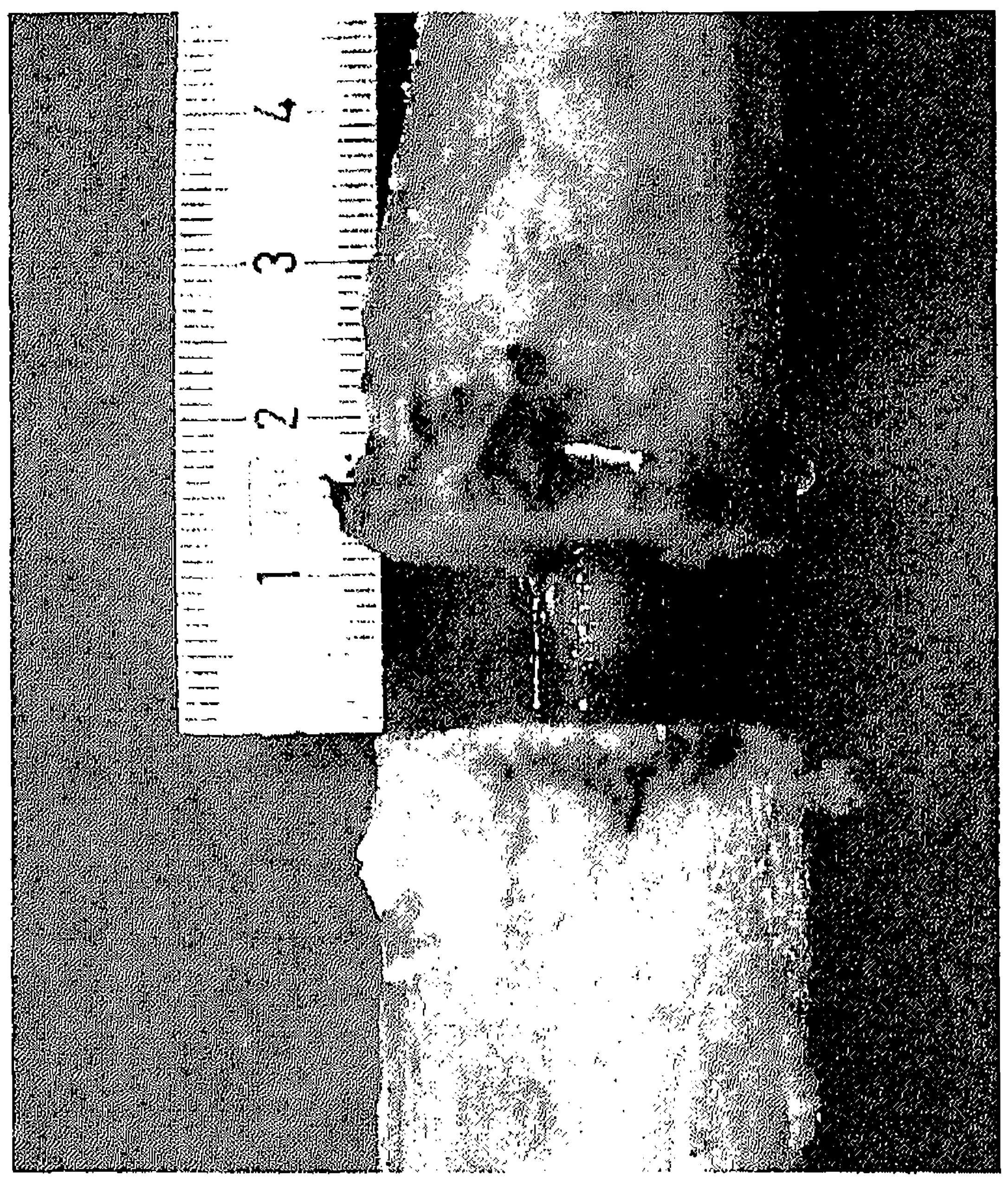

Figure 3: The bone defect created midshaft, simulating an unstable fracture.

Testing

All specimens were loaded through a rotation motor and a linear motor of a servo-pneumatic operated machine (SincoTec, Clausthal-Zellerfeld, Germany). The data from the work of the motors were registered with the PC-program DasyLab.

To assess compression forces exerted by the nails, axial distraction was applied with a force varying from 0 till 1500 N. The opening of the osteotomy under distraction was captured by a video-analysis system using two marking points placed on both sides of the osteotomy (Figure 4). By analyzing the relative movement of these points with the video system, the opening of the osteotomy can be calculated. As the video is synchronised with the testing machine, the precise moment of opening and the corresponding force can be determined. This force is equal but opposite to the compression force. To test stability of the compression, the distraction test was repeated after the other tests had been completed.

For torsional stiffness, torsion in the humeral axis was applied with four sinusoid cycles of 0.5 to 6.5 Nm with a frequency of 0.1 Hz. (Figure 5).

Bending stiffness (Figure 6) was determined with 4-point bending in 4 directions. The force was centrally applied with 4 sinusoid cycles of 10 up to 1000 N with a frequency of 0,1 Hz. With the bearings shifted over 0.03 m this gives a bending moment of 15 Nm. The mean of the results over the four directions gave the main outcome. The constructs with bone defect were tested under torsion and bending only. Endurance testing in bending of the nail-bone constructs with compression was done through cyclic loading in the medio-lateral direction with 100 cycles as described above. Endurance testing in torsion, also with 100 cycles, was done during torsional testing of the constructs with bone defect.

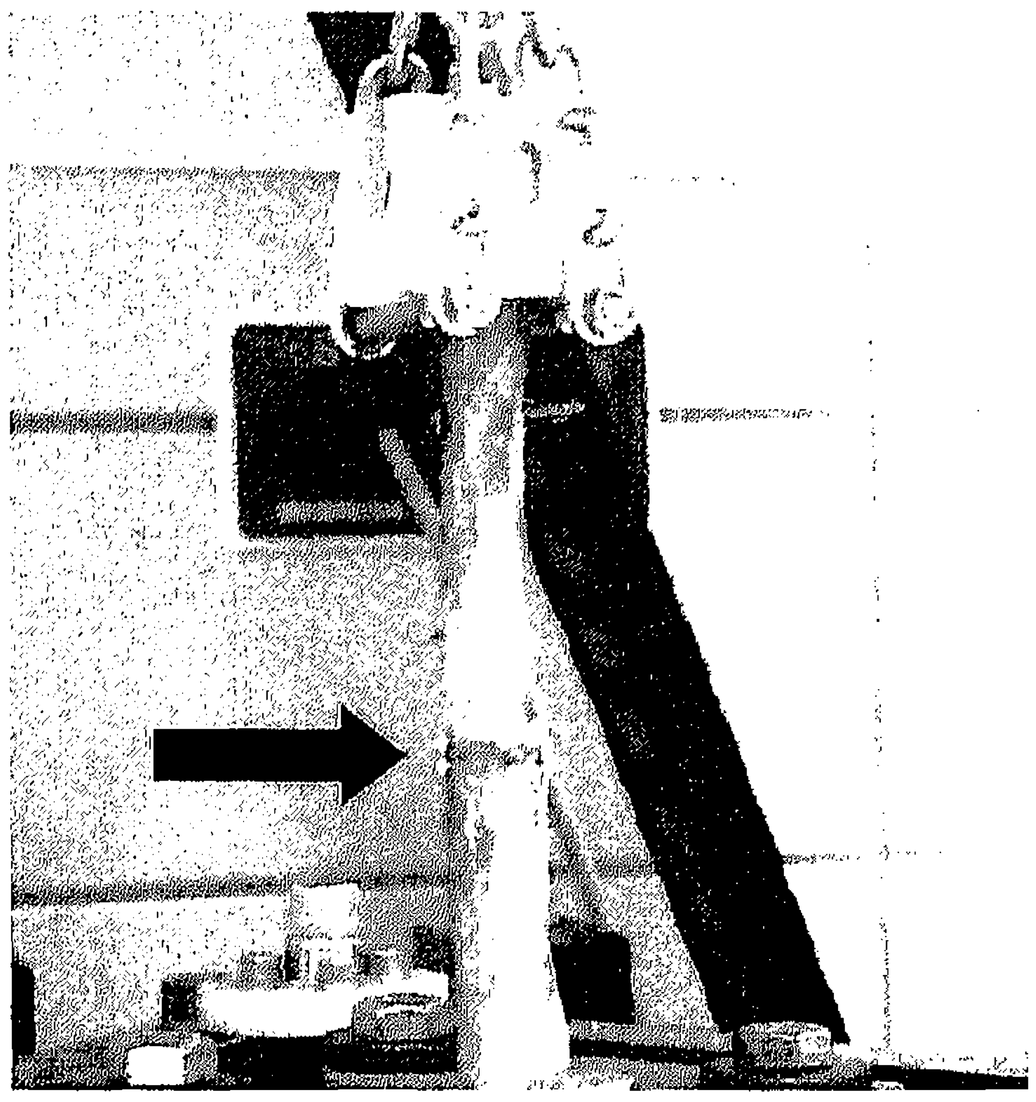

Figure 4: Testing of compression force through axial distracting with a force till 1500 N. Arrow indicates marking points

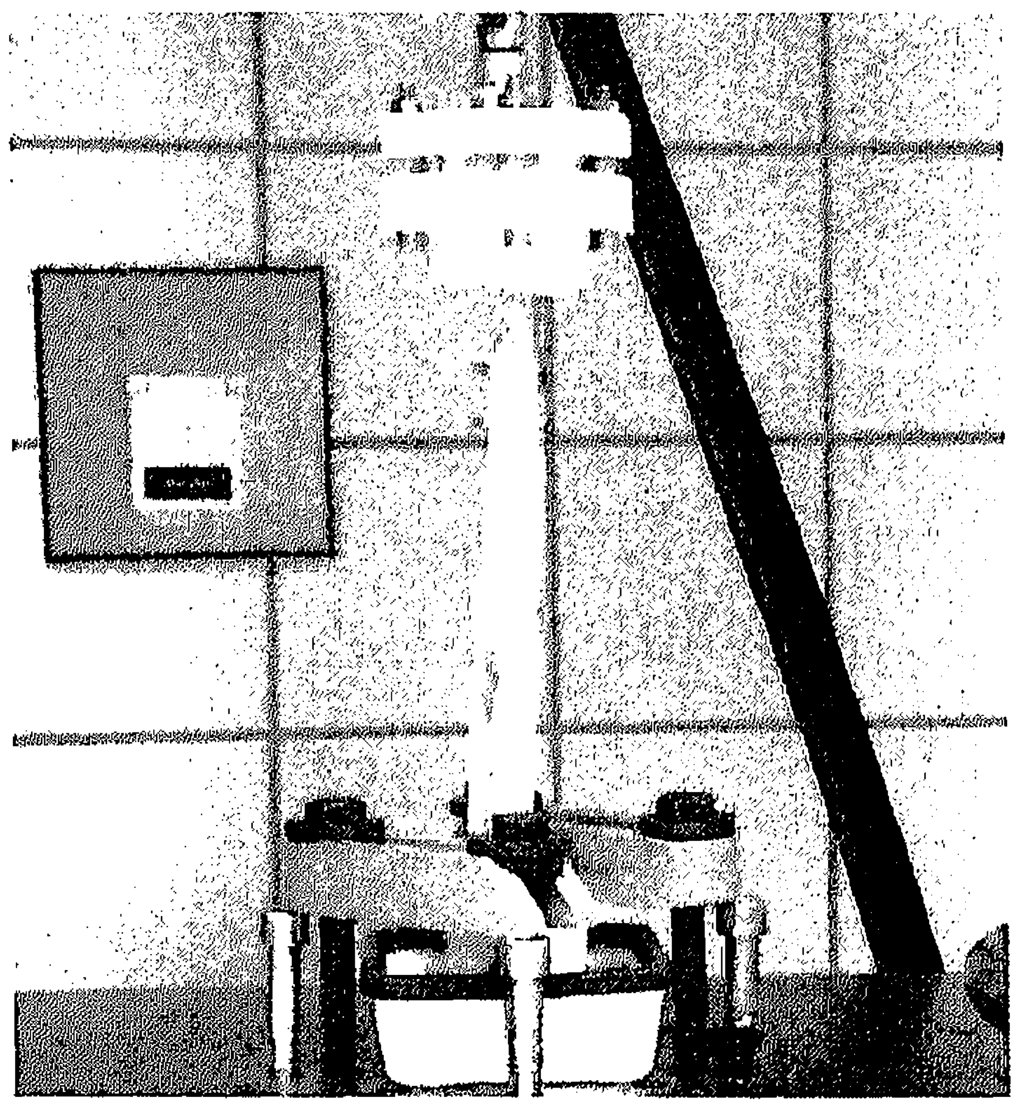

Figure 5: Torsional testing with a torsional moment of 6.5 Nm

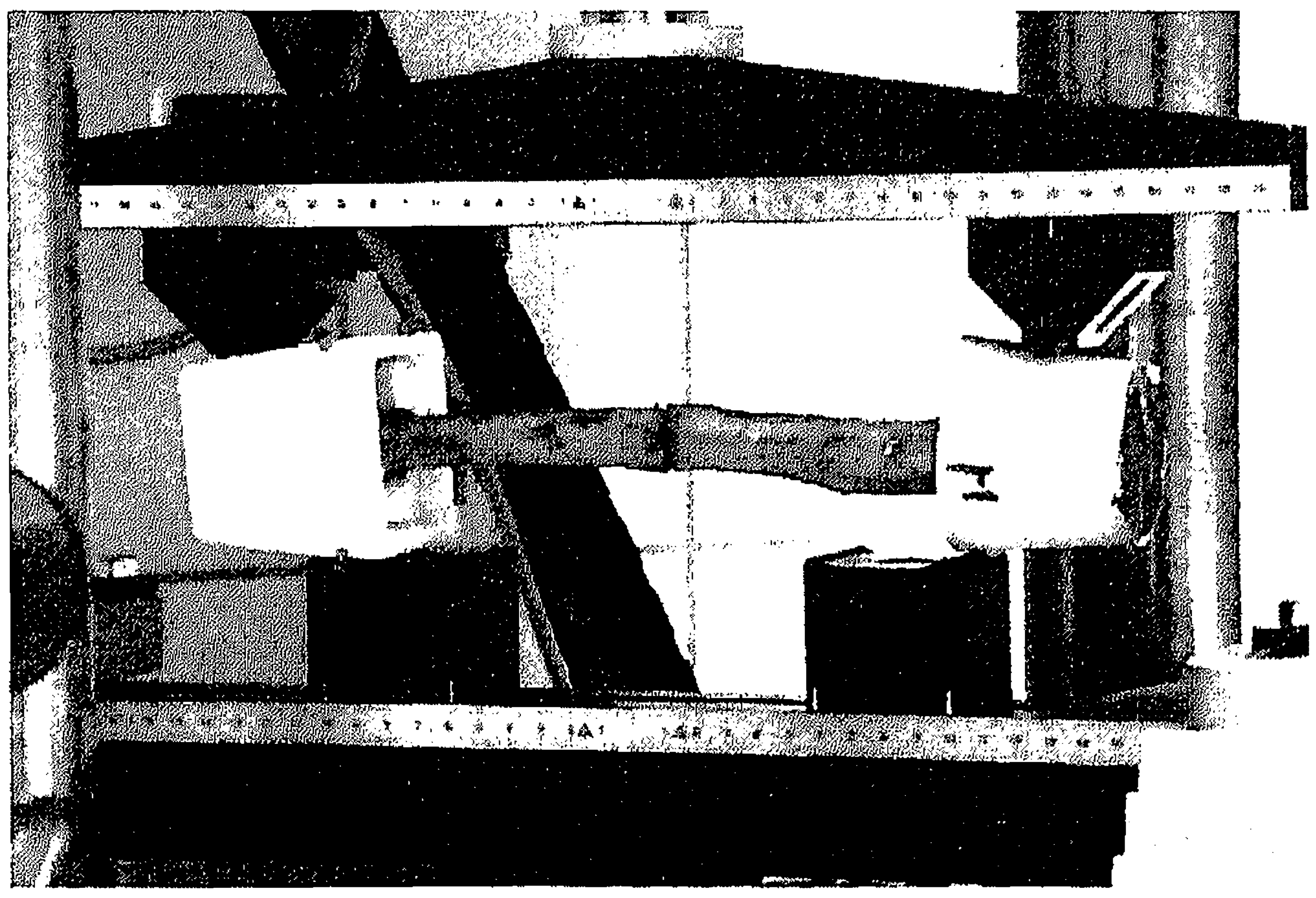

Figure 6: 4-point bending with a bending moment of 15 Nm.

Statistics

Results of each pair of cadaveric humeri from the same individual were analysed using Student's t-test for paired analysis. Level of significance was set at $p<0.05$. In case the results were not normally distributed, they were log-normalised and the geometric mean was calculated. 95% Confidence intervals (CI) were determined.

Results

Intact humeri

The mean BMD for the left humerus was 0.41 (SD 0.11) g/mm3 and for the right humerus 0.42 (SD 0.12) g/mm3 (difference = -0.01, 95%CI = -0.02 to 0.01, p=0.3) Intact humeri had a mean bending stiffness of 1.03 (SD 0.22) kN/mm for the left and 1.07 (SD 0.25) kN/mm for the right side (difference = -0.04, 95%CI = -0.11 to 0.03, p=0.3). Mean torsional stiffness for the left side was 1.64 (SD 0.55) Nm/° and 1.79 (SD 0.76) Nm/° for the right side (difference = -0.15, 95%CI = -0.35 to 0.05, p=0.2).

Axial distraction

Results are presented in Table I. Under axial distraction deformation in the osteotomy was less in the case of the TLN® compared to the UHN®. The difference however was not significant. After torsional testing and bending tests with cyclic loading in the medi-olateral direction the deformation in the constructs with UHN® was significantly more then in those with TLN®.

Table I: Mean (SD) opening of the osteotomy in mm before and after cyclic loading under axial distraction with 1500 N.

Opening of osteotomy (mm)	TLN	UHN	Difference	95 % Confidence Interval	p
Before cyclic loading	*0.08 (SD 0.03)* [a]	*0.23 (SD 0.17)* [a]	*-66 %* [b]	*-89 % to +3 %* [b]	*0.1*
After cyclic loading	*0.10 (SD 0.06)* [a]	*0.31(SD 0.18)* [a]	*-67 %* [b]	*-84 % to –37%* [b]	***0.01***

a Geometric mean. b Because of log-normalisation differences and CI ar expressed in percentages.

Bending

The bending properties are shown in Table II. Under compression the constructs with TLN® are significantly stiffer than those with UHN®. In the constructs with bone defect this difference was not significant. After cyclic loading in mediolateral direction no significant differences in deformation were found (Table IV). The nail-bone constructs with TLN under compression in bending reached 91% of the stiffness of the intact humeri, compared to 76% for the UHN. For the constructs with bone defect this was 60% for both nails.

Table II: Mean (SD) bending stiffness in kN/mm of nail -bone constructs and intact humeri with loading of 15 Nm.

Bending Stiffness in kN/mm	TLN	UHN	Difference	95 % Confidence Interval	p
With compression	*0.96 (SD 0.25)*	*0.80 (SD 0.25)*	*0.16*	*0.07 to 0.25*	***0.01***
With gap	*0.61 (SD 0.08)*	*0.57 (SD 0.11)*	*0.04*	*-0.01 to 0.08*	*0.2*
Intact Humeri	*1.05 (SD 0.22)*	*1.05 (SD 0.25)*	*0*	*-0.08 to 0.07*	*0.9*

Table III: Mean (SD) torsional stiffness in Nm/° of nail-bone constructs and intact humeri with loading of 6,5 Nm.

Torsional Stiffness in Nm/°	TLN	UHN	Difference	95 % Confidence Interval	p
With compression	*1.21 (SD 0.32)* [a]	*1.09 (SD 0.42)* [a]	*11 %* [b]	*-18 to + 50 %* [b]	*0.5*
With gap	*0.91 (SD 0.26)* [c]	*0.85 (SD 0.24)* [c]	*0.06*	*-0.02 to 0.15*	*0.2*
Intact Humeri	*1.72 (SD 0.61)*	*1.71 (SD 0.71)*	*0.01*	*-0.22 to 0.24*	*1.0*

a Geometric mean. b Because of log-normalisation difference and 95% CI are expressed in percentages. c Mean over 7 pairs, 1 pair broke during initial torsional testing.

Torsion

In torsional testing under compression the TLN® was more stiff than the UHN®. The difference however was not significant. Also with bone defect both nails were comparable in torsional stiffness. Figures are shown in Table III. After cyclic loading no significant differences in deformation were found (Table IV). In torsion the constructs with TLN had 78% of the stiffness of the intact humeri and the UHN 72%. For the constructs with bone defect this was 50% for both nails.

Table IV: Mean (SD) deformation of the nail-bone constructs after cyclic loading in bending and torsion.

Deformation after cyclic loading	TLN	UHN	Difference	95% Confidence Interval	p
Bending (mm)	*0.42 (SD 0.14)*	*0.48 (SD 0.23)*	*-0.06*	*-0.21 to 0.08*	*0.4*
Torsion (°)	*1.52 (SD 0.56)* [a]	*1.66 (SD 0.80)* [a]	*-0.14*	*-0.70 to 0.41*	*0.7*

a Mean over 7 pairs, one pair broke during initial torsional testing.

Discussion

We compared two humeral intramedullary compression nails concerning their stability against torsional and bending forces. We assumed that no differences exist between left and right bone of the same individual and we found no significant differences in bone mineral density and stiffness in four-point bending and torsion in the humeri.

We decided for a strictly paired analysis with random assignment of the nails to left or right humerus, as described by Blum et al. [3, 4, 5]. Other paired analyses have compared more than two implants using the same bone twice or more and have used nail types with various cross sectional diameter [7, 11, 20, 28, 32]. This leads to comparison of groups with smaller numbers, which can compromise statistic calculations.

The midshaft transverse osteotomy we used, simulates an unstable fracture type with small contact area which is preferentially operated and in which compression improves fragment adaptation and stability. Fracturing the humeri by bending or torsion might create fracture types not suited for compression. Furthermore a transverse osteotomy is easy to reproduce. A bone defect simulates a worst case scenario of a highly unstable fracture. The influence of contact between bone fragments in bending and torsion is eliminated. The stability of the constructs is then mainly determined by the bone-bolt and nail-bolt interface. In this way the implants are tested as two extremes of different situations possible in vivo: on one hand a model allowing full bone to bone contact with maximum transfer of load and unloading the implant; on the other no bone to bone contact with no transfer of load and maximum load on the implant [1, 16, 29].

In compressing the fracture, contact between both fragments is restored with a certain force. The exact compression needed for optimal bone healing however is not known. It also is very difficult to quantify. At the osteotomy differences in contact area remain and depending on the intramedullary position of the nail, apposition of fragments may need more or less effort. Therefore pressure gauges or a torque screw driver are not useful. Blum et al. used the metric scale on the compression device of the UHN® [4, 5]. Limiting factors here are the strenghth of the locking bolt and bone. Applying compression until the nail has migrated over a certain distance regardless of torque applied, may lead to bending or cutting out of the locking bolt. Therefore in our study we applied compression as in the clinical situation, by the feel. The surgeon turns the screwdriver till the fracture gap is closed and maximum resistance appears. Buhren et al compared the torque needed with that in tightening of a good fitting cortical screw [6]. As the feel of maximum torque is obvious and nails were implanted by the same person having clinical experience with these implants, variation in compression is limited. This constitutes a weak point in our study but it seemed the best compromise between scientific accuracy and feasibility.

We did not find a significant difference in opening of the osteotomy under distraction. The compression applied was similar for both nails and more then 1500 N, which is considered sufficient for a stable osteosynthesis [13, 21, 22, 23]. After cyclic loading, opening of the osteotomy with the TLN® was significantly less than with the UHN®. With the latter some compression is lost because of the play of the locking screws in the locking holes. Locking the screw in the oblong hole with an axial set screw leads to angular stability which explains the higher stability of the construct. Mittelmeier et al. in his experiments with a femoral compression nail using an axial set screw, also found that cyclic loading affected compression only minimally [19].

The TLN® was significantly stiffer in bending than the UHN®. In torsional stiffness no significant differences were found. We considered the compression over the fracture sufficient to withstand the torsional forces acting on the humerus in physiological circumstances. This is in accordance with the findings of Schopfer et al. that for stability in torsion in a transverse fracture the contact provided at the fracture site was more important than the nail's diameter [29].

In the unstable fracture simulation both in bending and torsion, no implant appeared superior. Also cyclic loading did not lead to significant differences in deformation. The forces applied lie well within the elastic region of the implants.

In bending, the TLN® under compression reached more then 90% of the stiffness of the intact humerus, the UHN® 78%. In torsion this was 78% and 72% respectively. Compared with the Russell-Taylor Nail® (RT) which reached 20% as described by Schopfer et al. both implants are true load sharing devices [28]. There is no risk for stress shielding as with a plate which can reach a stiffness of about 150 % of that of the intact humerus [31].

Comparing our results with other biomechanical studies on interlocking humeral nails is difficult. Mostly several implants are tested and methods, forces applied and calculation are not always described [15]. Seidel nails (SN) were found to be equally stable compared to double locked nails both in bending and in torsion [7, 11]. According to Schopfer et al. [28] and Zimmerman et al. [32] double locked nails were significantly stiffer in torsion than the SN. In the study of Blum et al. [3,4,5] the RT was less stable in torsion compared to the UHN® because of the initial rotational instability due to the play of the distal locking bolt. This varies between 4° and 30° [3, 4, 5, 20, 32]. The intrinsic instability of RT and SN is shown in the study of Mazirt et al. [17]. The primary instability of SN, RT and ACE® nail was explained by the "play" of the different locking systems. The plate is more stable in torsion according to Henley et al. [11]. In the analysis of Zimmerman et al. the plate was stiffer than all nails in bending and stiffer than all nails except the Orthofix nail, in torsion [32]. Torsional stiffness of the nail-bone constructs under compression for UHN® (1.20 Nm/°) and TLN® (1.26 Nm/°) (values before log-normalisation) were comparable with the stiffness of 1.27 Nm/° of the DC plate as measured by Zimmerman et al. [32] and 1.37 Nm/° as measured by Henley et al. [11]. These however were the maximal values reached at the yielding point of the construct under destructive torsion. Our values lay well within the elastic zone of the constructs.

As every in vitro biomechanical study, this study also has its drawbacks. We did not take the stabilizing role of the soft tissues into account [6, 14, 26]. A comminutive, unstable fracture is not just a defect. Bone fragments in combination with soft tissues may still allow some load transfer. With a reamed nail, reaming debris might have a stabilising effect also. Furthermore, as forces acting on the humerus in everyday life are not known, assumptions have to be made in in vitro testing. Both implants however, are tested in identical circumstances in a paired set-up. Therefore conclusions can be drawn concerning the inherent bending and torsional properties of these implants in combination with bone.

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CHAPTER X

General discussion and recommendations

I. Indications for operative treatment of humeral shaft fractures

The humeral shaft fracture constitutes only 1 to 5% of all human fractures (Healy et al. 1987, Link and Henning 1988, Kessler et al. 1996, Kelsch et al. 1997). Most of the time it concerns simple fracture patterns, type A or B according to the AO classification. In less then 18% C-type fracture are found. Less then 6% are open fractures (Link 1988, Nast-Kolb 1991, Tytherleigh-Strong 1998, Court-Brown 1998). In the above 50s, 80% of humeral shaft fractures are caused by a simple fall (Baron 1996). Combined with the lower anatomical demands for the humerus, this makes it the ideal bone for non-operative treatment. The Sarmiento brace allows early use of shoulder and elbow joint and can be considered the standard for treatment of humeral shaft fractures (Sarmiento 1977, 2000, Wallny 1997, Kayser 1986, Langenberg 1987, Helmreich 1987, Peeters 1987, Dufour 1989, Zagorski 1988, Koch 2002). Comparative studies with operative treatment confirmed the superior results of conservative treatment. Healing results are at least as good and, more importantly, complication rates are lower (Tuncay 1967, Ruedi 1974, Widmer 1974, Fasol 1983, Walny 1997, Klestil 1997, Camden 1992).

Despite these good results, high failure rates have been reported after non-operative treatment as well: Foulk et al. (1995) had a non-union rate of 39% and Christensen (1967) reported a failure rate of 41%. Some circumstances therefore will request operative treatment of humeral shaft fractures. Two main factors determining fracture healing are vascularisation and stability. Both factors can be influenced by local conditions depending on the original trauma: comminutive fracture type, open fracture with severe disturbance of local vascularisation, concommittant lesions of neurovascular structures. Non-operative treatment is not possible or at least very difficult in these circumstances. The patient self however is the main factor in deciding on operative or non-operative treatment. With a brace the fracture is stabilised but active movement is necessary to maintain allignment and enhance vascularisation; which stimulates bone healing. Non co-operative individuals such as drug addicts, alcoholists and demented elderly will not comply with the instructions given necessary for successful brace treatment. In this case a stable osteosynthesis is preferred. Also with obesitas, a brace can not maintain fracture reposition properly and therefore operative treatment is indicated. Nursing polytraumatised patients should be possible without any concern about dislocation of fracture in a brace. Patients who stay longer on intensive care or have concommittant lesions are unable to exercise properly, loosing the benefit of brace treatment. In fact obesitas and multiple fracture are considered a contra-indication for conservative treatment of humeral fractures (Jensen 1995).

Apart from good fragment alignment with good bone contact, vascular supply of the fracture fragments is necessary for uneventful healing. Vascularity is compromised with smoking and alcohol abuse (Rosen 1990, Foulk 1995, Jupiter 1998). In older patients with osteoporosis fracture healing is still active but the process appears to be more susceptible to disturbing factors (Chao 2004). In case of such pre-existing compromised fracture healing process, operative fracture fixation combined with early functional treatment stimulating local vascularisation and hence bone healing, is the therapy of choice. Considering this, the generally accepted indications for operative treatment of humeral shaft fractures are: failure to maintain reposition, neurovascular lesion, floating elbow, (impending) pathologic fractures, open fractures, polytrauma, non-union and uncooperative patients.

Different techniques are available for operative treatment of patients with humeral shaft fractures. Operative treatment of fractures is based on the following principles: anatomical reduction of fragments, stable fixation and postoperative immediate active exercises of the affected limb and joints. The plate complies with these demands. Of the intramedullary techniques only locking intramedullaary nails provide for sufficient stability allowing immediate use of the arm. Elastic nailing techniques usually require an external supporting device or temporary immobilization.

In this chapter we discuss the use of (reamed) intramedullary locked compression nailing in the treatment of patients with humeral shaft fractures. Anatomical aspects, biology, biomechanics, complications, advantages and disadvantage will be highlighted against the background of other established techniques like plate osteosynthesis and elastic nailing.

II. Operative treatment of humeral shaft fractures

A. Implant considerations: plate vs. intramedullary nails

Plate osteosynthesis has been the standard for treatment of humeral shaft fractures until now. Only elastic nailing techniques like Hackethal bundle nailing and Ender nails provided for a useful alternative for open reduction and plating during the last decades of the past century. A plate with interfragmentary compression creates a strong and stable construction allowing early use of the arm with healing rates of more then 90% (Widmer 1974, Andre 1984, Bell 1985, Michiels 1986, vander Griend 1986, Rommens1989, Kwasny 1990, Nast-Kolb 1991, Dabezies 1992, Heim 1993, Hegelmaier 1993, Bèzes 1995, Siebert 1996, Hee 1998, Dayez 1999, Paris 2000). Humeral locking nails combine the minimal invasive technique of elastic nailing with the stability of a plate and comply with the principles of operative fracture treatment mentioned above. With locking nails likewise healing rates of more then 90% have been achieved (Habernek 1991, Riemer 1991, Eberle 1992, Jensen 1992, Crolla 1993, Kempf 1994, Kelsch 1997, Thomsen 1998, Gaullier 1999, Crates 1998, Blum 1997,1998,2001, Rommens 1195a,b, 1998, Petsatodes 2004, Goessens 1996, Verbruggen 2002, Fernandez 1999,2004, Ikpeme 1994, Ingman 1994, Vecsei 2001).

Prospective randomised comparative trials on operative treatment of humeral fractures are scarce. Only two randomised controlled trials comparing plate and locking nails have been published. Furthermore results are not consistent. McCormack (2001) concluded that plating is better than nailing because of lower re-operation rates. Most re-interventions with nails were because of protruding nails into the subacromial space, disturbing shoulder function. Unfortunately the author does not mention whether these nails migrated during follow-up or they were left protruding into the shoulder joint with introduction. In the former case an unstable implant has been used, in the latter it is a technical error. Healing and functional results were comparable. Chapman (2001) found disturbed shoulder function with antegrade nailing and disturbed elbow function with plating. Healing and complication rates were comparable. Some retrospective studies also resulted in different conclusions. Lin et al (1998) found significantly higher non-union rates with the plate and better function with the nail. Mulier et al. (1997) compared nails with plates. With both techniques complication rates were rather high: 30% non-union with plate and 20% with the nail, radial nerve palsy after plating in 16% of cases. Functional results of the shoulder were better with plating than with nailing. Conclusion was that operative treatment of humeral fractures is still associated with a high frequency of complications. Meekers et al. (2002) found higher non-union and re-operation rates with the nail.

Two prospective trials comparing nails with elastic nailing have been reported. Chiu et al (1997) compared plate with and without bone graft and elastic nails. Healing results were better after elastic nailing than after a plate with cancellous bone graft. Plate without cancellous bone graft gave the worst results. Chao (2005) compared the plate with elastic nailing and interlocked nailing in a prospective trial. Elastic nailing had the better results: less operation time, less blood loss and healing results were as good. Locking nails had longer operation times but also significant less blood loss compared to the plate.

B. Anatomical considerations

1) Surgical approach for plate osteosynthesis

The standard access to the humerus is the dorsal approach described by Henry. This allows a complete overview of the dorsal aspect of the humerus between both metaphyses. Disadvantage is the risk of damaging the radial nerve, which crosses the dorsal aspect of the humerus. The deltoideopectoral approach is used in case of fractures of the proximal 3rd. With this approach the axillary nerve is at risk. Alternative approaches are the medial and extended lateral approach. The medial access is seldom used because it is at the compression site of the humerus. It is an excellent alternative in case of former dorsal interventions with higher risk of damaging the radial nerve due to scar tissue surrounding the nerve. With this approach however the musculo-cutaneous nerve is jeopardized. With the extended lateral approach again the radial nerve is at risk.

Each of these approaches demands extensive dissection of soft tissues, destructing vascular structures with risk of disturbed bone healing and infection. A minimal invasive approach like with intramedullary techniques provides for a valid alternative in this respect. Nevertheless these approaches appear to have their own disadvantages.

2) Surgical approach for intramedullary nails

a. Insertion point morbidity - antegrade nailing

Antegrade introduction of nails in the humerus seems self-evident. The wide proximal medullar canal makes nail introduction easy. Despite introduction through rotator cuff and cartilage, several authors report good functional results after antegrade nailing (Kelsch 1997, Riemer 1991, Seidel 1989,1993, Crolla 1993, Crates 1998, Ikpeme 1994). Recovery of shoulder function however appeared to be longer than 6 months. Other reports mention a substantial loss of shoulder function (Robinson 1992, Varley 1995, Bain 1996, Hemms 1996, Flinkkillä 1999, Cox 2000, Ajmal 2001).

The insertion point originally described by Seidel just medial to the greater tubercle is situated in the avascular zone of the rotator cuff, which may lead to definite damage and functional loss. To prevent rotator cuff damage, other insertion points have been suggested: the anterior acromial access in the better vascularised part of the rotator cuff could prevent shoulder function impairment (Riemer 1993, Crates 1998). With this access the coraco-acromial ligament has to be divided. In doing so the subacromial space is decompressed, which is beneficial for shoulder function. This portal lays also more in line with the medullar canal. Therefore less cortical stress occurs preventing iatrogenic fractures. Accurate closing of the rotator cuff incisions is advised. According to Faragos (1999) however this would not have influence on eventual loss of function.

Minimal incisions without exposing and splitting the deltoid or supraspinate muscle were suggested by Ikpeme et al. (1994). He reported shoulder function to be satisfactory till excellent according to the Neer score in 88% of the cases. We agree with Ikpeme that in order to prevent damaging the rotator cuff, minimal incisions without wide exposure are in order. Dimakopoulos (2004) described a more lateral entry point for antegrade nailing away from the rotator cuff through the greater tubercle. Results were good but in our opinion a higher risk for iatrogenic fractures exists.

Apart from functional impairment, distraction of the fracture with nail introduction is reported as complication of antegrade nailing. Non-union in 33% of cases has been reported (Hemms and Buhllar 1996, Ajmal et al. 2001, Flinkkillä et al. 1999). Retrograde nailing is considered the better alternative. Distraction of the fracture during nailing was already a problem described by Küntscher (1967). Using thick nails to be impinged, it happened that these nails jammed in the narrower distal part of the medullar canal and, driving the nail deeper, distracted the fracture.

Much depends on the implant itself. A massive nail like the SN will damage the rotator cuff more then an elastic nail, which can be introduced through a stab incision. Migrating nails because of insufficient locking system like the SN and RT will perforate the rotator cuff and cause impingement. Though it is generally accepted that perforating the cuff must have an influence on shoulder function, the literature is not consistent. Some studies could demonstrate a significant loss of shoulder function after antegrade nailing (Flinkkillä 1999, Chapman 2000). However, despite a significant difference in absolute shoulder function with the contralateral side, Flinkkilä (2004) did not find a clinical relevant impairment of shoulder function after antegrade nailing after a mean follow-up of 8 years. We found a similar phenomenon in a subgroup of elderly patients where antegrade nailing did not influence shoulder function.

b. Insertion point morbidity - retrograde nailing

The complications associated with antegrade nailing made several authors adopt retrograde nail introduction. This has the advantage of being a completely extra-articular procedure. Functional results both for shoulder and elbow were good to excellent. (Rommens 1995a,b, 1998, Blum 1997, 1998, 2000, 2001, Linn 1997). Compared to antegrade nailing the retrograde way leads to faster recovery of shoulder function (Ingman and Waters 1994).

In our experience with the TLN antegrade nailing appeared to have a negative influence on shoulder function. Neer score was significantly less than with retrograde nailing. Elbow function was hardly impaired through retrograde nailing. A later study on 77 fresh fractures showed no significance but a trend remained (Verbruggen 2002). Scheerlinck (2002) compared in a prospective study antegrade nailing with the UHN® and the retrograde technique with the MVN®. Shoulder function was significantly worse after antegrade nailing.

With retrograde nailing, peri-articular ossification and adhesions in the elbow region disturbing elbow function, also have been described (Dereume 1973, Durbin 1983, Brumback 1986, Schatzker 1987, Rommens 1995a, Loitz 1998, Schratz 1998).

According to Faragos (1999) no sufficient arguments exist in favour of either way of introduction. Despite controversial statements, we feel that transarticular introduction should be avoided and retrograde introduction should be preferred whenever possible.

c. Iatrogenic fractures

Though a complication of both ante and retrograde nailing in 2 till 22% of cases, it is mostly associated with retrograde nailing. We had overall about 9% iatrogenic fractures but about 17% with retrograde introduction. Rommens (1998) mentioned 8%, Fernandez (1999,2004) 10,7% and later 7%. These fractures do not necessarily lead to instability. A fissure through the dorsal cortex without disturbing fracture stability has minimal consequences. If stability is disturbed, fixation with encircling wire loops or plate and/or screws is necessary. In our series most iatrogenic fractures did not need fixation. The greater part of these fractures can be explained by the rather high number of different surgeons involved in the study, demonstrating the learning curve of this technique. Iatrogenic fracture also has been described with antegrade nailing. With introduction through the lateral portal just medial from the greater tubercle, the rigid nail can take support on the acromion while the nail tip is pushed against the medial cortex creating stress in the lateral cortex (Ruf 1993, Barnes 1993). Another cause of peroperative fractures is introduction of a thick rigid nail without sufficient reaming. In our series one such fracture occurred.

A secure operating technique is mandatory to prevent these fractures. The introduction hole has to be prepared very carefully. For retrograde nailing two portals have been described. The supracondylary access and the olecranon fossa access. Introducing the nail should be done with gentle rotating movements to prevent stress building in the cortices. Because with the supracondylar portal the entry point lays excentrically from the humeral medullar canal there is a higher risk of fracture. With the entry point in the roof of the fossa olecrani the nail can be introduced more in line with the canal, which reduces cortical stress (Lin 1997, 1999). After changing to this access we saw less iatrogenic fractures. Two types of supracondylar region based on the offset of the condylar block exist. Depending on this off set, the portal for nail introduction lays more supracondylar or in the fossa to allow easy nail introduction in line with the medullar canal (Lin et al. 1999). Nevertheless careful introduction remains mandatory.

Both accesses do weaken the distal humerus. The supracondylar portal however seems to decrease stability of the distal humerus less than the fossa portal. Differences however were not significant (Strothman 2000, Blum 2000b).

Rather then confirm one self exclusively to one way of introduction, the fracture pattern and patient should indicate the way of nailing. Nailing from the shorter into the longer fragment is biomechanically more stable (Lin 1998). Nail introduction from the longer into the shorter fragment however preserves the fracture haematoma, is technically easier and prevents destabilisation of the smaller fragment by iatrogenic fractures (Küntscher 1967, Brumback 1986, Ward 1989). This means proximal and mid shaft fractures have to be nailed from distal, distal factures from proximal.

d. Structures at risk

In treating humeral fractures the radial nerve always has been the main structure at risk. Radial nerve lesions can be caused through the primary trauma. In 2 till 26% of the cases one has to take a pre-operative radial nerve palsy into account (Holstein 1963, Böstman 1985, 1986, Rommens 1989, Vansteenkiste 1989, Alnot 1989, Kwasny 1991, 1992, Takami 1999). Discussion exists whether exploration is necessary or one can remain expectative. Kwasny et al. (1991, 1992) preferred early exploration both with primary and secondary radial nerve paralysis. Complete transsection of radial nerves occurs mostly with high-energy humeral fractures, which are open most of the time (Ring 2004). Severe damage to the nerve is seldom and primary nerve reconstruction does not lead to good results. Therefore one can remain expectative. In 90% of the cases spontaneous recuperation occurs with non-operative treatment (Böstman 1985, 1986, Sonneveld 1987, Vansteenkiste 1989, Alnot 1989). If the radial nerve does not recover within 3-4 months, exploration is warranted. In some cases however where primary exploration was carried out the nerve was fixed in the fracture and had to be released.

At risk are fractures with severe displacement and so-called "longitudinal" fractures in the distal third of the humeral shaft especially spiral type fractures (Holstein 1963, Böstman 1985,1986, Vansteenkiste 1989, Alnot 1989, Samardzick 1990, Takami 1999). In this case early exploration is indicated. Radial nerve exploration is not without risk. Further damage to the nerve is possible (Böstman 1985, 1986, Sonneveld 1987, Samardzic 1990). Rommens (1989) mentioned 3 cases of incomplete recovery and blamed the extensive dissection of the nerve during the procedure. Samardzic (1990) even reported 12 cases.

If an operative stabilization is necessary, with an open technique nerve exploration easily can be carried out. With nailing however the risk exists that with reaming and/or nail introduction the radial nerve will be severely damaged. Open exploration of the nerve is mandatory in these cases (Faragos 1999).

Postoperative radial nerve lesions are significantly less compared to the plate, 5% compared to 10%. Secondary radial nerve palsy is often considered a reason for exploration (Rommens 1989, Vansteenkiste 1989, Kwasny 1991,1992). One of the causes of radial nerve damage may well be the manipulation of the extremity during patient positioning and operative preparations. It is recommended to leave the immobilization device on until desinfection is started (Rommens 1998).

In contrast to tibia and femur where the locking sites do not interfere with anatomical structures that could be damaged, locking nailing the humerus may compromise some essential anatomical structures. Proximal locking of nails introduced antegrade is done through an aiming device. At the level of the proximal locking site for most nails the axillary nerve is in danger. The risk is less in the case of locking bolts oriented obliquely. Both in the latero-medial and in the antero-posterior way branches of the axillary nerve can be jeopardized (Lin 1999, Evans 1993, Blum 2002, Albriton 2003, Prince 2004). Antero-posterior locking jeopardizes also the long biceps tendon. With retrograde nailing it is generally advised to position the nail tip at 2 cm distally from the surgical neck to prevent damage to the axillary nerve. It is important not to let the drill engage to far in the surrounding soft tissue both medially and posteriorly to prevent axillary nerve damage. Despite the obvious risk for the axillary nerve, only one lesion has been reported in the literature (Svend-Hansen 1998). Distal interlocking is best done in the anteroposterior direction. Care has to be taken not to introduce the bolt too far medially because of median nerve and brachial artery. In case of locking in the latero-medial direction the radial nerve is at risk. (Kolonja 2002). If this way of interlocking is absolutely necessary sufficient access has to be created to allow screw introduction under direct sight. Blyth (2003) reported damage to the musculocutaneous nerve after distal locking in the antero-posterior direction.

Using locking humeral nails one has to be aware of the potential damage to different structures in this region. Anatomical knowledge and a meticulous technique therefore are mandatory.

C. Biological Considerations

1. Plate.

Plate osteosynthesis provides for rigid fixation of fracture fragments creating enough stability to allow early functional treatment of the humerus. Beside the risk of damaging vascularity through the extensive approaches, the plate itself disturbs the biological process of fracture healing. Stability against shear forces is achieved through maximal friction between plate and bone. This disturbs vascularization of periosteum causing fracture healing problems. Absolute stability with interfragmentary compression was deemed necessary to allow "primary fracture healing". This however is in general a slow process based on internal remodelling. Therefore consensus existed not to remove plates before 1,5 to 2 years (Perren 2003). Absolute stability however leads to "stress shielding" which in turns causes weakening of the bone. This is inversely proportinal to the rigidity of constructs. (Uhthoff 1971, Bradley 1977, Sarmiento 1980). Refracture risk after plate removal is substantial. "Stress shielding" actually is nothing else but bone necrosis (Perren 2003). The concept of biological osteosynthesis with bridging plating and secure manipulation of soft tissues was a first reaction against meticulous anatomical reduction and fixation of every fragment with vast exposure and soft tissue damage (Gerber 1990). To minimize disturbance of periosteum plate design has been changed from the DC plate over the L(ow) C (ontact)-DC plate and the latest development the LC plates, a no-contact plate. Minimal invasive techniques with percutaneous plate and screw introduction in the mean time have been developed for treatment of metaphyseal fractures of tibia, femur and proximal humerus, thus diminishing soft tissue trauma (Frigg 2001, Perren 2003, Stoffel 2003, Wagner 2003). For the humeral shaft a technique for medial plating has been described but experience remains limited (Livani 2004).

Despite the concept of biological osteosynthesis and minimal invasive plating techniques interference with peripheral vascularisation cannot be excluded completely. Intramedullary techniques still have the advantage of being minimally invasive with preservation of periosteal and peripheral vascularization wich is of primordial importance for fracture healing.

2. Nail

With tibial and femoral nailing, introduction of thick nails after power reaming is generally accepted because of high stability and possibility of immediate weight bearing. In the case of humeral shaft fractures however it remains controversial not in the least due to negative experience with the SN. This nail however was thick and rather rigid. To introduce the SN power reaming was necessary also because of the distal locking system that needs sufficient space to allow the flanges to be spread. RT nails, though reaming was an option, could be introduced unreamed most of the time. The concept of biological osteosynthesis demanded preservation of endomedullar vascularization.

The $UHN_{®}$ therefore was essentially developed as an unreamed implant. Reaming reduces cortical blood flow but introduction of an unreamed nail also interferes with endomedullar vascular structures (Klein 1990, Grundness 1993). Moreover, healing results of unreamed nailing have not been better. Endovascular structures are less important for fracture healing and even after complete destruction, bone healing continues. After a fracture with damage to nutrient artery and endovascular structures, a centrifugal blood flow develops with increase of peripheral and periosteal blood flow allowing periosteal bone healing with formation of callus (Trueta 1974, Whiteside 1977, Strachan1990, Reichert 1995). The good healing results of the TLN® and other reamed nails demonstrate that reaming does not have a negative influence on fracture healing. As with femoral and tibial nailing, it might even benefit from it (Finkemeier 2000, Tornetta 2000, Bhandari 2000). Reaming debris is a viable product being pressed in the fracture during the reaming procedure, which stimulates bone healing (Frölke 2000, 2001).

Heat necrosis due to reaming has been reported with humeral nailing. Three cases have been described (Ochsner 1998, Remiger 1997). In all, it concerned very narrow intramedullar canals exactly as in cases with heat necrosis of the tibia. Medullar canals narrower than 9 mm are prone for complications (Riemer 1994). Pre-operative planning remains essential. Alternative techniques should be looked for in the case of narrow canals, such as elastic nailing or plating. In the case of vast soft tissue lesion and fractures with extensive comminution and thus damage to both endo- and periosteal vascular structures, primary treatment with external fixation should be considered. If internal fixation is possible a locking nail is the better option.

D. Biomechanical considerations

1. Mechanics of plate and nail

Both the mechanical function of plate and intramedullary nail require transfer of loads between bone fragments and implant.

With the traditional plating techniques this is gained through compression. Compression is used in two ways. First the plate is screwed to the bone to raise maximum friction between plate and bone to prevent displacement of fragments. As long friction is higher than the shear and bending forces, fragments remain in place. Secondly, prebending (preloading) the plate provides compression over the whole fracture. Interfragmentary compression generates torsional stability due to friction between fragments (Perren 1979, Modabber 1998, Tepic 1995, Tencer 1993). Experimentally forces between 800 and 1400 N can be applied by the DCP (Allgöwer 1969, Willenegger 1971, Perren 1969). However, the exact amount of compression to achieve primary bone healing never has been determined.

Stiffness characteristics of the plate are mainly determined by the working length. This is the distance between 2 fixation points. Bending stiffness is inversely proportional to the square of the working length, torsional stiffness inversely to the working length itself. This depends on number and configuration of screws. Because of fixation with screws close to the fracture, the plate has a shorter working length. Bending stiffness therefore is higher. Removing central screws from a plate reduces stiffness significantly. Separation of screws and length of plate have only little effect. Torsional stiffness is determined by the number of screws (Stoffel 2003, Tencer 1993).

With intramedullary nails, stability is gained through internal splinting of the bone. Bending stiffness depends on stiffness of the nail itself and the interference between nail and bone. Locking screws mainly determine torsional stiffness. Stiffness of a nail is mainly determined by the "area moment of inertia" (I), which is a measure for distribution of material in an object around a certain axis (Modabber 1998, Tencer 1993). We can illustrate this with the TLN® and UHN®, a stainless steel tube and a solid titanium rod repectively. The TLN® constructs are significantly stiffer in bending than the UHN® constructs. The thicker 9 mm ends do not play a significant role in the tests because the working length of the nails is determined by the section between both locking bolts. The nail's thinner central part of 7,6 mm lies between those 2 bolts.

The bending stiffness of the nails itself depends on the Elastic Modulus "E" which is specific for each material: E_{steel}=180 GPa, $E_{titanium}$=110 Gpa. Bending stiffness is defined as *E x I* ; in which "E" is the Elastic Modulus and "I" the Second Moment of Area.

The second moment of area "I" is defined through the formulas:

$$I_{rod} = \frac{\pi}{4} R^4$$

for a solid rod and:

$$I_{tube} = \frac{\pi}{4}\left(R_o^4 - R_i^4\right)$$

for a cannulated nail, in which R_o is the outer diameter and R_i the inner diameter.
The relation between bending stiffness of both nails then, is given through the following formula:

$$\frac{E_{TLN}}{E_{UHN}} \times \frac{I_{TLN}}{I_{UHN}}$$

As the TLN® is a tube with an outer radius of 3,8 mm and an inner radius of 3,0 mm, and the UHN® is a solid rod with radius of 3,75 mm, this gives the following equation:

$$\frac{180}{110} \times \frac{(3.8^4 - 3.0^4)}{3.75^4} = 1.05$$

Both nails have almost the same bending stiffness. The differences in bending stiffness of the nail-bone constructs therefore are mainly determined by the bone-bone, bone-bolt and bone-nail interference. Higher stability in case of the TLN® might be gained through the stronger 4,5 mm locking bolts. It also explains why no significant differences were found in the tests with bone defect. In this case applied loads are transferred directly through the implant. A solid unreamed nail therefore is still a good option in the treatment of humeral fractures.

The plate has a higher bending and torsional stiffness compared to most nails. In the case of solid nails torsional stiffness is higher (Henley et al. 1991,Waite, Zimmerman et al. 1994). Elastic nails have the lowest stiffness both in bending and in torsion (Henley 1991, Zimmerman 1994).

Locking systems of humeral nails determine rotational stability. The spreading flanges of the Seidel nail (SN) were found to be equally stable compared to double locked nails both in bending and in torsion (Henley et al.1991, Dalton et al. 1993). Other studies reported a significantly higher torsional stiffness for double locked nails (Schopfer et al. 1994, Zimmerman et al. 1994). Play of the locking screws as with the RT and SN significantly diminishes torsional stiffness (Zimmerman 1994, Mølster 1997, Blum 1999, 2000a,b, Mazirt et al. 1999).

Non-locked nails like the inflatable Fixion® nail and Trueflex Nail® are rotational completely unstable during in vitro tests, bending stiffness is comparable with conventional locking nails (Blum 2005, Dalton 1993).

In an unstable fracture situation plate and intramedullary nail provide similar fixation stability but the nail has a significant higher load to failure (Chen et al. 2002).

2. Compression nailing of humeral fractures

With conventional locking nails rotational forces cannot be excluded completely. Stiffness of plates appears to be higher than intramedullary nail because compression creates higher fragment interference. Compression nailing therefore also will enhance torsional stiffness of the nail-bone construct. In the lower extremity compression forces prevail but in the upper arm only muscle activity has a stabilizing effect (Latta 1980, Bühren 2000). Therefore, compression has to be applied by active means. Kaessmann introduced compression in intramedullary nailing (Kaessmann 1970, Stapert 1983). The main advantage of compression nailing was improved stability, especially against torsional forces. Compression forces between 600 and 900 N could be applied. The indications for intramedullary nails could be expanded and thinner nails could be used making extensive reaming no longer necessary (Kaeßman 1966, 1969, 1974, Ritter 1987, 1991, Mittelmeier 1989). A more simple compression technique is the axial setscrew, as used by Derweduwen (1979), Ritter (1987, 1991) and Mittelmeier (1989, 1990). Cortical bone is able to endure compression forces till 5000 N and with a nail active compression forces till 2500 N are possible (Ritter 1982, Mittelmeier 1989, 1990).

Due to supposed necrosis and resorption at fragment ends during fracture healing, compression was thought to disappear rather quickly after osteosynthesis. The experiments of Perren et al. (1969b) proved however that compression with plates decreases gradually over several months. No sudden drop due to bone resorption or necrosis was seen. The diminishing of the compression is explained through adaptation of the bone to the new situation by gradual bone remodelling. A similar phenomenon probably exists in compression nailing. Through elasticity of bone and nail and through the play of the locking screws the compression diminishes gradually while callus is formed.

The UHN® with compression had a significant raise in stiffness compared to the same nail without compression (Blum 2000). Compression nailing with TLN® and UHN® creates torsional stiffness comparable with the stiffness of the DC plate. Depending on the implant, a compression nail reaches 78 to 91% of the stiffness of the intact humerus. Even in an unstable fracture model intramedullary nails reach 40 to 60% of the stiffness of intact humeri (Blum 2006). RT nails only reach 20% (Schopfer 1994). TLN® and UHN® under compression are genuine load sharing implants without risk of stress shielding like the plate, which reaches 150% of the stiffness of the intact humerus (Waite 1991).

III. Special Case: Geriatric patients

A stable osteosynthesis allowing full early functional use of the extremity is an interesting alternative for the older patient because they cope less with loss of function of the arm. Very good healing and functional results have been achieved with plate osteosynthesis but osteoporotic bone provides less grip for the screws leading to loosening of the plate (Franck 2003, Pereles 1997, Ring 1999, Strømsøe 2004). Implant loosening of 2 till 12% in distal humeral fractures has been described (Lill 2000). With plating in general loosening in 2% has been mentioned. Longer plates with more screws solve this problem but this leads to even larger incisions, compromising soft tissues and periosteum even more (Ring 1999, Franck 2003, Stromsoe 2004). Bone cement augmentation can prevent screw loosening but the use of it in the elderly is not entirely without problems. Its handling and keeping it out of the fracture is difficult, the exothermic reaction in hardening of the cement can disturb the fracture healing process and it is a large foreign body which constitutes a problem in revision surgery or with infection (Ring 1999, 2004). Schuhli nuts enhance the screw stability by using the principle of angular stability as good as bone cement but add additional steps to the procedure (Jazrawi 2000, Ring 1999, 2004). The recently developed locking plate techniques combined with screws with a larger core diameter and a smaller pitch are a further step to the solution to this problem (Ring 2004, Strømsøe 2004). The large incisions and soft tissue damage however remain.

Elastic nails are less stable. Furthermore in the elderly the medullary canal is wider and in consequence less stability is achieved with these elastic nails (Riemer 1994). The lower holding power in osteoporotic bone can also lead to the dislocation of the nails, losing the reposition. Depending on the introduction site this can compromise shoulder or elbow function. A double locked intramedullary nail provides better stability in both axial and rotational directions and makes it possible to use the arm immediately post-operatively. It does not depend on the holding of the locking screws in the bone to maintain reposition as a plate does. Even if locking screws loosen, fracture stability can be maintained sufficiently by the nail (Strømsøe 2004).

In the older osteoporotic patient bone healing process is still active but slower. At the same time bone healing process appears to be more susceptible to disturbing factors. An adequate reduction of the fracture with sufficient bony contact therefore is necessary (Chao 2004). If these conditions can be met with non-operative treatment by a brace and functional therapy, it is the therapy of choice. If not, a minimal invasive technique with an intramedullary compression locking nail is the best alternative. As development of a non-union in this particular population will lead to a substantial disability it is of utmost importance to decide for operative treatment as soon as it becomes clear that non-operative treatment will not lead to the expected result (Dallek 1982, Fasol 1983, Ring 1999). For humeral fractures, if after six to eight weeks no callus formation is seen, the chance that this fracture will heal eventually is very low (Mast 1975, Jupiter 1998).

Functional results in this particular patient group appear to be independent of introduction site even if compared with the non-affected side. Antegrade nailing is thus safe in the older patient. It is technically easier with shorter operation time and supine or beach chair position of the patient is less demanding from the anesthesiologic point of view.

IV. Special Case: Non-union

Humeral fractures normally heal well, irrespective of technique used. In treating humeral non-unions it is important to define "non-union". General consensus exists that if a conservatively treated humeral facture does not show any sign of callus after 6 till 8 weeks, it is very unlikely that this fracture will heal (Klenerman 1966, Mast 1975, Jupiter 1998, Foulk 1995, Fasol 1983). The traditional period of 4 till 6 months to diagnose delayed union therefore can be shortened by halve. In this case an osteosynthesis should be done.

Non-union rates of up to 40% have been mentioned for humeral nails (Hemms 1996, Svend-Hansen 1998,Flinkkilla 1999, Cox 2000, Ajmal 2001). Though some authors see this as typical for and thus as an argument against humeral nailing, in our opinion it is the result of insufficient implants and/or insufficient technique. The lack of stability of the SN has been demonstrated before. Extra-stabilization has been described with plates and staples over the fracture to treat non-unions developing after intramedullary nailing (Emmerson1998, Wu 1998, Lin 2002). Antegrade nailing can cause distraction over the fracture when the nail engaged in the distal fragment (Hemms 1996, Flinkkilla 1999, Ajmal 2001). The humerus does not tolerate distraction. A maximum of 10 mm has been mentioned in the literature but other authors advise only 5 mm (Delong 1989, Kwasny 1990, Chen 2000). This phenomenon has been known since Küntscher. A proper operation technique will prevent this. If introduction in the distal fragment should be difficult, careful reaming the distal fragment makes nail insertion possible. Even with the UHN® hand reamers are provided to ream the canal if necessary. A compression system as provided with TLN® and UHN® makes it possible in the case of distraction, to come to apposition of fragments again. Results of other series on humeral nailing with healing rates well above 90% contradict the idea of a higher tendency to non-union with nailing of the humerus.

Treating an established non-union with nails appears to be a challenge. The success of intramedullary nails in the treatment of tibial and femoral non-unions prompted the use of interlocking nails in humeral non-union. This however was not as successful. Also exchange nailing in humeral non-union did not lead to success (Rosen 1990, McKee 1996). Open debridement with cancellous bone graft and stable fixation with a plate leads to good healing results and is still considered the standard (Chacha 1974, Fattah 1977, Loomer 1976, Foster 1985, Healy 1987, Barquet 1989, te Velde 2001, Marti 2002). Küntscher (1967) has introduced reamed nailing of humeral non-unions. Reaming was necessary to allow thick intramedullary nails be impinged with a maximum of bony contact. According to Küntscher failure of nailing was caused by using too thin a nail. Lack of rotational stability seems more likely however (Christensen 1976). Reaming itself can cause non-union in the case of medullar canals smaller then 9 mm (Riemer 1994). As stated higher, in this case an alternative technique should be looked for. In the case of unreamed nailing however as with the UHN®, union rates both in the case of fresh fractures and non-union have not been better (Dujardin 2000).

Most series reporting on humeral nailing of non-unions mention a high failure rate (Schwarz 1995, Dujardin 2000, Flinkkilä 2001, Ilyas 2003). Some authors concluded that compared to the plate, locking nails are not suitable for the treatment of humeral non-unions. However, mostly different nails were used in the same study, among these Humeral Locking Nails® and Russell-Taylor Nails®. These implants however lack rotational stability and therefore are less suited for treatment of humeral non-union (Dalton1993, Schopfer 1994, Emmerson 1998, Mazirt 2000, Dujardin 2000). In combination with debridement and cancellous bone graft, healing results of nails are comparable to the plate (Lin 2000, Kesemenli 2002, Martinez 2002). Comparative studies could not demonstrate differences in healing rate between plate and nail but nailing suffered fewer complications and had faster healing (Wu 1992, Martinez 2004). Treatment resistant humeral non-unions have successfully been treated with repetitive compression and distraction with external fixation (Lammens 1998, Raschke 1998, Patel 2000).

Our results and those published before suggest that the healing problems in humeral non-union are primarily caused by lack of "biology" instead of lack of stability. In fact every non-union of the humerus should be treated as an atrophic pseudarthrosis. Debridement and cancellous bone graft almost always results in healing regardless the technique used.

An established non-union therefore should be treated with extensive debridement and stable fixation. Though a humeral nail in combination with a cancellous bone graft is an option, we recommend the use of a compression plate.

V. Treatment protocol

A. Patient factors

1. Healthy patient, single fracture

The humeral shaft fracture is best treated non-operatively. A Sarmiento brace provides for enough stability allowing functional treatment with good healing results with a minimum of complications. The only reason for operative treatment in this case is explicit patient wish or uncooperative patients who do not comply with the demands of brace treatment.

2. Patient at risk for compromised healing (alcohol abuse, osteoporosis, smoking, old age, obesitas)

In this case a higher risk for development of non-union exists. This specific category of patients is generally un-cooperative which makes treatment with a brace difficult. The higher risk for non-union demands a stable fixation with good bony contact between fragments. The intramedullary nail is the ideal implant in this case. Also in case of obesitas, which is considered a contra-indication for the brace because it is very difficult to maintain reposition, an IM-nail should be used.

3. Complicated follow-up

In the case of inadequate reposition of the fracture or when after 6 to 8 weeks of conservative treatment radiological signs of callus formation are still not visible, operative treatment should be considered. As in this case non-union is not yet established, a reamed nail will provide for sufficiently stable fixation.

B. Fracture type

1. Simple fracture types (AO type A and B)
Most humeral shaft fractures are simple fracture types. Spiral type fractures provide for a large contact surface, which is favourable for conservative treatment. Transverse and short oblique fractures (AO type A3) have a higher tendency to non-union because of smaller contact area and distraction. These should be considered for primary operative stabilization in any case if the distraction is greater then 1 cm. An intramedullary nail with compression is in this case is the best option.

2. Comminutive fracture type (AO type C)
These are high energy lesions often combined with severe damage to surrounding soft tissues. Depending on the extend of damage, the IM nail or even the External Fixator are preferred to the plate.

3. Multiple fractures (floating elbow, bilateral fractures, lower extremity fractures)
Multiple fractures are a contraindication for non-operative treatment. An early stabilization will make early mobilisation and functional treatment possible, which favours bone healing. The IM nail in this case is also recommended, specifically if humeral fractures are combined with fractures of the lower extremity and crutches have to be used for revalidation.

4. (Impending) Pathological fracture
In the literature this indication is considered ideal for intramedullary nailing. Short operation times with minimal invasive stabilisation is the least demanding technique for cancer patients. Nailing provides for a stable osteosynthesis leading to sufficient pain relief and early recovery of function.

C. Soft tissues

1. Neurovascular lesion.
In the case of primary neurological lesion immediate exploration is not necessary and conservative treatment is warranted. In most of the cases spontaneous recuperation will occur. In the case of secondary radial nerve palsy exploration is necessary combined with stable fixation of the fracture. Because of the extended access, plate osteosynthesis seems evident but an IM nail is a good alternative depending on the preference of the surgeon. In case of traumatic vascular lesion a stable osteosynthesis is necessary to allow restoration of vascular structures. These lesions often occur with vast soft tissue trauma and extensive dissection is necessary. The plate seems evident under these circumstances but the nail is a valid alternative.

2. Open fracture
Open fractures till Gustillo-Anderson type II are easily treated with an IM nail. Type III

open fractures are mostly high-energy traumata disrupting soft tissues and creating comminutive fracture types. In this case primary treatment with an external fixator should be chosen to allow soft tissues and bone vascularisation to recover. In a second stage a definite stabilization easily can be done with IM nailing.

D. Polytrauma

Depending on other lesions and general condition of the patient, primary treatment should focus on stabilization of the vital parameters of the patient according to ATLS rules. Fractures should be treated according to the orthopaedic damage control principles. Depending on the fracture type, operative treatment of humeral shaft fractures may be postponed or is done with an external fixator. If condition of the patient allows, a primary IM osteosynthesis may be carried out because it is the less demanding technique in time and blood loss compared to a plate. Elastic nails are in this case a valid alternative for primary stabilisation because of the simple technique with short operation time and minimal bloodloss.

VI. Conclusion

An overall agreement exists that humeral shaft fractures should be treated non-operatively. Based on the good results gained with the Sarmiento brace, this technique is considered the standard of non-operative treatment of the humeral shaft. General agreement also exists on the indications for operative treatment. If treated operatively a stable osteosynthesis is mandatory. The plate has been considered the golden standard for a long time. Despite the disadvantages of large incisions with soft tissue damage with higher risk for infection and non-union, and the risk of radial nerve palsy, good results have been achieved with this technique until now. Exactly because of these possible complications, an intramedullary technique appears to be a suitable alternative. Infection rates and radial nerve palsies are diminished and non-union rates remained the same. Humeral locking nails also have their specific complications: antegrade nailing disturbs shoulder function; retrograde nailing has a higher risk of iatrogenic fractures, migrating locking bolts and nails etc. Intramedullary nailing alone appears not to be the ideal treatment for humeral non-union because also the biology of the non-union should be improved by cancellous bone graft

Rather than to stick to one technique, one should choose, out of the scala of different implants possible for the humerus, the technique best fitted for the indication. In the case of a simple, isolated humeral shaft fracture we recommend the Sarmiento brace, provided the patient is co-operative. If after 6 to 8 weeks no radiological sign of healing is visible, operative intervention is necessary. The intramedullary locking nail is a good implant for the treatment of fresh acute humeral shaft fractures. The fracture level should determine antegrade and retrograde introduction: distal third fractures should be nailed antegrade and midshaft and proximal third fractures retrograde. Double locked nails have our preference. In the case of an established non-union debridement and definitive stabilization with a plate in combination with a cancellous bone graft is the therapy of choice.

Biomechanically stability of humeral nails can be improved significantly in the case of transverse or short oblique fractures by using compression. An axial setscrew proves to be the more stable option.

The intramedullary nail has become a more or less standard implant in the treatment of humeral fractures. The literature and our own experience however show that not all problems in treating those fractures are solved by this implant. It is a complementary technique with its own specific advantages and drawbacks. The technique of osteosynthesis should be chosen according to the condition of the patient and the disturbance of local biology by the injury. Therefore it is to the surgeon, experienced in the treatment of humeral fractures, aware of his own skills and being familiar with implants available and the technique to apply them, to decide for which indication and how he will use the humeral intramedullary nail.

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CHAPTER XI

Summary / Samenvatting

In this thesis the concept of reamed nailing of the humerus is discussed. After an overview how intramedullar nails in general and humeral locking nails in particular have been developed during the last century in *Chapter I*, the development and design of the Telescopic Locking Nail® is presented in *Chapter II*. *Chapter III* describes the technique of intramedullar nailing. *Chapter IV* is an overview of treatment modalities for humeral shaft fractures. The methods most used are discussed, from thoraco-brachial casts over hanging cast and Sarmiento brace to the plate osteosynthesis and intramedullary locking nails.

In *Chapter V* we report on the concept of reamed intramedullary nailing with the TLN®. The first results of a dutch multicentre trial are presented and the late functional results discussed. A total of 78 patients with 79 humeral shaft fractures were included: 50 were fresh fractures, 17 secondary interventions for non-union and 12 were (impending) pathological fractures. The concept of a straight, reamed humeral nail appears to be feasable in clinical praxis. Healing results are good with a healing rate of 98% for fresh fractures. Non-unions however had a healing rate of only 46%. The most important complication is the iatrogenic fracture in 9%. Long term functional result are good with a score of good to excellent according to the Neer score in 89% of cases. A significant difference exists between antegrade and retrograde nail introduction. Shoulder function after antegrade introduction scores significantly less compared with retrograde introduction. Therefore retrograde introduction is advised whenever possible.

Chapter VI describes the results of treatment of 77 fresh humeral fractures. Healing and functional results confirm the results achieved in the previous study. Though no significance exists, antegrade nailing did result again in worse shoulder function compared to retrograde nailing.

In *Chapter VII* we discuss the use of the TLN® in a specific patient group, the elderly. As this population increases steadily in our society, trauma surgeons will be confronted more and more with fractures typical of this patient group, which include humeral shaft fractures. In this chapter we evaluate the use of a reamed locking nail in the treatment of humeral shaft fractures in the elderly. Good healing and functional results are achieved. In this particular case even without difference between antegrade and retrograde introduction. As the older patient is becoming more fit and his demands concerning proper treatment are higher, a more aggressive treatment of humeral shaft fractures allowing early return to their former environment may be the better option.

Non-union still is the most important complication in the treatment of humeral shaft fractures. Though being a minimal invasive procedure, the humeral nail appeared not to be the solution for prevention of this complication. It also appeared not to be the proper implant for the treatment of this complication. As described in *Chapter VIII*, non-union of the humeral shaft is caused by lack of biology rather then lack of stability. Therefore a humeral nail is an option in the treatment of humeral non-union provided it is combined with a cancellous bone graft.

Stability is the key question in the treatment of fractures. If a humeral fracture is treated with an intramedullary nail, the nail and bone form a construct that has to withstand forces acting on the humerus. In general these are bending, distracting and rotational forces. In *Chapter IX* the TLN® is compared to the UHN® concerning bending and torsional stiffness with and without compression. The TLN® appeared to be significantly stiffer in bending. Compression applied with the axial set screw appears to be more stable option. In torsion and in the unstable fracture situation no significant differences between both implants were recorded.

Chapter X discusses the use of humeral intramedullary locking nails with their specific technique and complications. With the TLN® good results have been achieved compared with other humeral implants. The humeral nail appears not to be the ideal implant solving all problems in the treatment of humeral fractures. It has its own specific complications which the user has to be able to deal with in order to come to successful treatment.

In dit proefschrift wordt de behandeling van humerusschachtfracturen door middel van een geboorde intramedullaire pen behandeld. Na een overzicht van de ontwikkeling van intramedullaire pennen in het algemeen en van de intramedullaire humeruspen in het bijzonder, gedurende de laatste eeuw in *Hoofdstuk I*, wordt in *Hoofdstuk II* de ontwikkeling en het concept van de Telescopic Locking Nail® voor de humerus voorgesteld. *Hoofdstuk III* beschrijft de techniek van de intramedullaire osteosynthese van de humerus.

Hoofdstuk IV is een overzicht van de meest gangbare technieken voor de behandeling van humerusschachtfracturen. De verschillende methodes van niet-operatief tot de laatste ontwikkelingen op gebied van intramedullaire osteosynthese worden beschreven.

In *Hoofdstuk V* worden de eerste resultaten van de TLN® in een Nederlandse multicentre trial gepresenteerd. In totaal werden 78 patiënten met 79 fracturen geïncludeerd, 50 waren acute fracturen, 17 secundaire behandelingen wegens non-union en 12 (dreigende) pathologische fracturen. Fractuurheling was goed met 98% consolidatie voor de acute fracturen. Bij de non-unions was dit slechts 47%. De late functionele resultaten waren eveneens goed te noemen, met een goed tot excellent resultaat volgens de Neer score in 89% van de gevallen. Schouderfunctie was significant slechter bij antegrade introductie vergeleken met retrograde introductie. Retrograde nagelintroductie heeft daarom onze voorkeur.

Deze resultaten werden bevestigd in een tweede studie van 77 verse humerusschachtfracturen beschreven in *Hoofdstuk VI*. Consolidatie in 96% met eveneens goede tot excellente functie volgens de Neer score in 90%. Tussen antegraad en retrograad nagelen bestond geen significant verschil, maar er was wel een trend zichtbaar.

Hoofdstuk VII beschrijft de resultaten van een specifieke patiëntengroep nl. de ouderen. Aangezien deze een steeds belangrijker deel van onze patiëntenpopulatie uitmaken, zullen traumatologen steeds meer met voor deze groep specifieke fracturen geconfronteerd worden. Humeruschachtfracturen horen daarbij. De resultaten van de TLN® in deze patiëntengroep zijn goed te noemen, zowel qua heling als qua functie. De oudere patiënt is steeds fitter en stelt hogere eisen aan zijn behandeling. Een meer aggressieve behandeling van humerusschachtfracturen bij de oudere patiënt zou wel eens geïndiceerd kunnen zijn om deze sneller naar zijn vertouwde omgeving te laten terugkeren.

Non-union is nog steeds de belangrijkste complicatie bij de behandeling van humerusschachtfracturen. Alhoewel een minimaal invasieve techniek, bleek de intramedullaire pen niet aan de verwachtingen ter voorkoming van non-unions te voldoen. Ook voor de behandeling van een pseudarthrose is de humeruspen, geboord of ongeboord, niet het geschikte implantaat. Zoals beschreven in *Hoofdstuk VIII* ontstaat een non-union van de humerus eerder door gebrek aan "biologie" dan door gebrek aan "mechanica". Daarom kan een intramedullaire humeruspen gebruikt worden in de behandeling van non-union op voorwaarde dat hij gecombineerd wordt met een spongiosa plastiek.

Bij de behandeling van fracturen is stabiliteit hoofdzaak. Als een humerusfractuur wordt behandeld met een intramedullaire pen, vormt deze met de humerus een constructie, die de krachten die normaal op de humerus inwerken moet weerstaan. Dit zijn voornamelijk buig-, distractie-, en rotatiekrachten. In *Hoofdstuk IX* testen we de TLN® op gebied van buigingsstijfheid, torsiestijfheid en compressie in vergelijking met de UHN®. Er bestaat een significant verschil in buigingsstijfheid met compressie tussen TLN® en UHN® ten voordele van de TLN, doch niet op gebied van torsiestijfheid. In de onstabiele fractuursituatie is er geen significant verschil zowel met compressie als met botdefect. Compressie met een axiale setschroef blijkt wel de meest stabiele oplossing te zijn.

In *Hoofdstuk X* worden de resultaten van TLN® en ander implantaten bediscussieerd. In vergelijking met andere humerusimplantaten presteert de TLN® minstens even goed.

De humerus grendelpen blijkt echter niet het ideale implantaat te zijn voor de behandeling van alle problemen die bij humerusfracturen kunnen optreden. De humeruspen heeft zijn eigen specifieke complicaties waar de gebruiker zich van bewust dient te zijn en die hij, als hij ermee geconfronteerd wordt, ook moet kunnen oplossen.

DANKWOORD

Bij het afronden van een proefschrift past het eenieder die ook maar iets te maken heeft gehad met de totstandkoming ervan te bedanken voor zijn hulp, steun of gewaardeerde medewerking. Dit betekent dat ik iedereen die meegewerkt heeft aan dit proefschrift of die het gevoel heeft dat hij of zij bij het schrijven van dit proefschrift een rol heeft gespeeld, hartelijk wil danken. Een aantal mensen verdient natuurlijk een speciale vermelding.

Zonder een goede basis kom je nergens in het leven. Mijn ouders, broers en zussen hebben mij mede gevormd en gemaakt tot wie ik nu ben. Zonder hun steun en waardering zou ik nooit de lange weg tot chirurg tot een goed einde hebben gebracht. Terugkijkend op mijn jeugd- en studiejaren kan ik alleen maar vaststellen dat een warm nest waar je altijd kan op terug vallen, belangrijk is om je doel te bereiken.

De kiem van de traumatologie werd in Gasthuisberg gelegd door Prof. Broos en Prof. Rommens. Het is dan ook fantastisch dat zij beiden bij dit proefschrift betrokken zijn. Prof. Broos als lid van de beoordelings- en promotiecommissie en Prof. Rommens als copromotor. Na een klassieke AO-scholing in Leuven en Garmisch-Partenkirchen bracht mijn promotor Jouwert Stapert me alle knepen van de intramedullaire osteosynthese bij. Hij maakte me ook duidelijk dat de natuuur mild is en dat patiënten in vele gevallen uiteindelijk genezen, niet zozeer dankzij maar ondanks ons ingrijpen als chirurg. Mijn tweede promotor Peter Brink doet niet zo aan gevleugelde uitspraken. Hij weet wel als geen ander lijnen uit te zetten en structuur aan te brengen. Onder zijn impuls werd de trauma-afdeling van het azM verder gestructureerd en uitgebouwd tot een goed draaiend geheel.

Flexibiliteit is een onmisbare eigenschap bij het werken in teamverband. De traumatologen van het azM hebben overduidelijk aangetoond dat het hen daaraan niet ontbreekt. Paul, Stefan, Wilbert, Sven, Wietse en Martijn moesten af en toe een tandje bijsteken wanneer ik zonodig achter de computer moest. De betrokkenheid van de overige stafleden van de afdeling Algemene Heelkunde bleek uit het regelmatig terloops informeren naar hoe het nu met "het boekje" zat. Een betere stimulans is er niet.

Al degenen die de gegevens verzamelden en mee verwerkten dienen natuurlijk ook te worden vermeld. Marco Goessens had reeds een groot deel van de patiëntengegevens in kaart gebracht. Er moest alleen nog wat mee gebeuren. Christiaan van Rij en Sven Adriaens onderzochten een groot deel van de patiënten verspreid over het hele land. Vanuit het Instituut voor Anatomie voorzagen Prof. Henk Van Mameren en Arno me van de nodige kadaverhumeri. De medewerkers van de afdeling Radiologie en Nucleaire Geneeskunde verzorgden de radiografiën en DEXA's van de preparaten. Het was nooit een probleem om dit even snel tussendoor te doen. Dipl.-Ing. Werner Sternstein van het biomechanisch lab in Mainz stelde het onderzoeksprotocol op en voerde de metingen feilloos uit.

Tot slot verwijs ik naar een van de stellingen horend bij het proefschrift van mijn promotor Jouwert Stapert: "het schrijven van een proefschrift en het opdragen daarvan aan een levenspartner is een veel te omslachtige manier om zijn genegenheid tot uitdrukking te brengen". Ik ben het daar volledig mee eens.

CURRICULUM VITAE

Jan Verbruggen was born in Reet, Belgium on 11-02-1962. After he graduated from the Onze-Lieve-Vrouwcollege in Boom, he started his medical studies at the Catholic University of Leuven. After his third year he worked for 5 weeks as a volunteer in the mission post of Faladjé, in the Republic of Mali. In the sixth year the elective in surgery was followed at the University of Pretoria in the H.F. Verwoerd Hospital and in the Kalafong Hospital in Pretoria, South-Africa. He earned his medical degree at June 30th 1987 and started his training in general surgery at the University Hospitals Leuven on August 1st 1987 under Prof. J. Gruwez and later Prof. P. Broos. During his training he worked in the following affiliated hospitals: the Sint-Jozefziekenhuis Mortsel (Dr. M. Van Baden and Dr. K. Vandeputte †), the Sint-Jansziekenhuis Genk (Dr. G. Clyncke and Dr. E. Neville) and the Sint Maartensgasthuis Venlo, the Netherlands (Dr. H. de Smet). After finishing his general surgical training, he started a training in trauma surgery at the Department of Trauma-, Hand- en Reconstructive Surgery of the Kreiskrankenhaus in Garmish-Partenkirchen, Germany (Prof. Dr. Med. K. Neuman†) and later as fellow at the Department of Surgery of the University Hospital Maastricht (Prof. J. Stapert). In 1998 he worked as Oberarzt in the Department of Traumatology of the University Hospital Aachen, Germany (Prof. Dr. Med. O. Paar). In 1999 he joined the staff of the Surgical Department of the University Hospital Maastricht where he works as trauma surgeon since then.

Jan Verbruggen is married to Viviane Maesen and together with their children Jan jr., Christiaan, Jasmine and Maurits they live in the beautiful green village of Zutendaal, Belgium.

APPENDIX

Appendix 1: Participating hospitals in the trial

- ☑ Academisch Ziekenhuis Maastricht
- ☑ Groene Hart Ziekenhuis, Gouda
- ☑ Leyenburg Ziekenhuis, Leiden
- ☑ Medisch Centrum Leeuwarden
- ☑ Medisch Spectrum Twente, Enschede
- ☑ Sint-Franciscus Gasthuis, Rotterdam
- ☑ Sint-Ignatius Ziekenhuis, Breda
- ☑ Slotervaart Ziekenhuis, Amsterdam
- ☑ Zaans Medisch Centrum “De Heel”, Zaandam

Appendix 2: The Neer and Morrey Score

NEER SCORE		MORREY SCORE	
ITEMS	***POINTS***	***ITEMS***	***POINTS***
PAIN	35	PAIN	30
FUNCTION STRENGTH REACHING STABILITY	30 10 10 10	STRENGTH	15
RANGE OF MOTION FLEXION EXTENSION ABDUCTION EXTERNAL ROTATION INTERNAL ROTATION	25 6 3 6 5 5	RANGE OF MOTION EXTENSION FLEXION PRONATION SUPINATION	37 8 17 6 6
ANATOMY	10	STABILITY	6
		FUNCTION	12
RESULTS		*RESULTS*	
EXCELLENT	90-100	EXCELLENT	95-100
SATISFACTORY	80-89	GOOD	80-95
UNSATISFACTORY	70-79	FAIR	50-80
FAILURE	<70	POOR	<50

Appendix 3: Biomechanical definitions.

Bending stiffness: The resistance of an object to an applied bending moment. It increases with the moment of inertia of the cross-section of the object and with the modulus of elasticity of the material (E), and decreases with length. Units are Nm/mm (Newton meter per millimeter).

Elastic modulus (Young's modulus): The ratio of stress to strain of an object, in the elastic region. Units are MPa (Megapascal).

Cyclic loading: Repetitive loading of an object within its elastic limits and below its failure load.

Force: a quantity that produces acceleration of mass. A body at rest or at constant velocity has no net force acting on it. Units are N (Newton).

Four-point bending: In this arrangement the load is distributed between two points of application on the beam. Here the bending moment between the two loading points is constant. This arrangement is advantageous in biomechanical testing where one might be uncertain as to the strongest or weakest point in a region and wishes not to influence the test by locating the maximum bending moment at a specific place.

Moment arm: The perpendicular distance from the center of rotation of a mass to the line of action of the applied force.

Moment: a force acting at a distance on a body with a defined center of rotation, which causes the body to rotate. Units are Nm (Newton meter).

Polar moment of inertia: A mathematical term describing how the mass of an object is ditributed about the axis about which the torque is applied. An object with its material located far from the loading axis, will be torsionally stiffer than an object with the same type and quantity of material which is closer to the loading axis. For a cylinder or rod, $J = \pi r^4/2$, with r = radius of the object. Thus a solid rod whose radius is twice as large as another of the same material will have a polar moment of inertia that is 16 times as large. If both rods have the same length, the larger rod will be 16 times as rigid in torsion as the smaller rod. Units are mm^4.

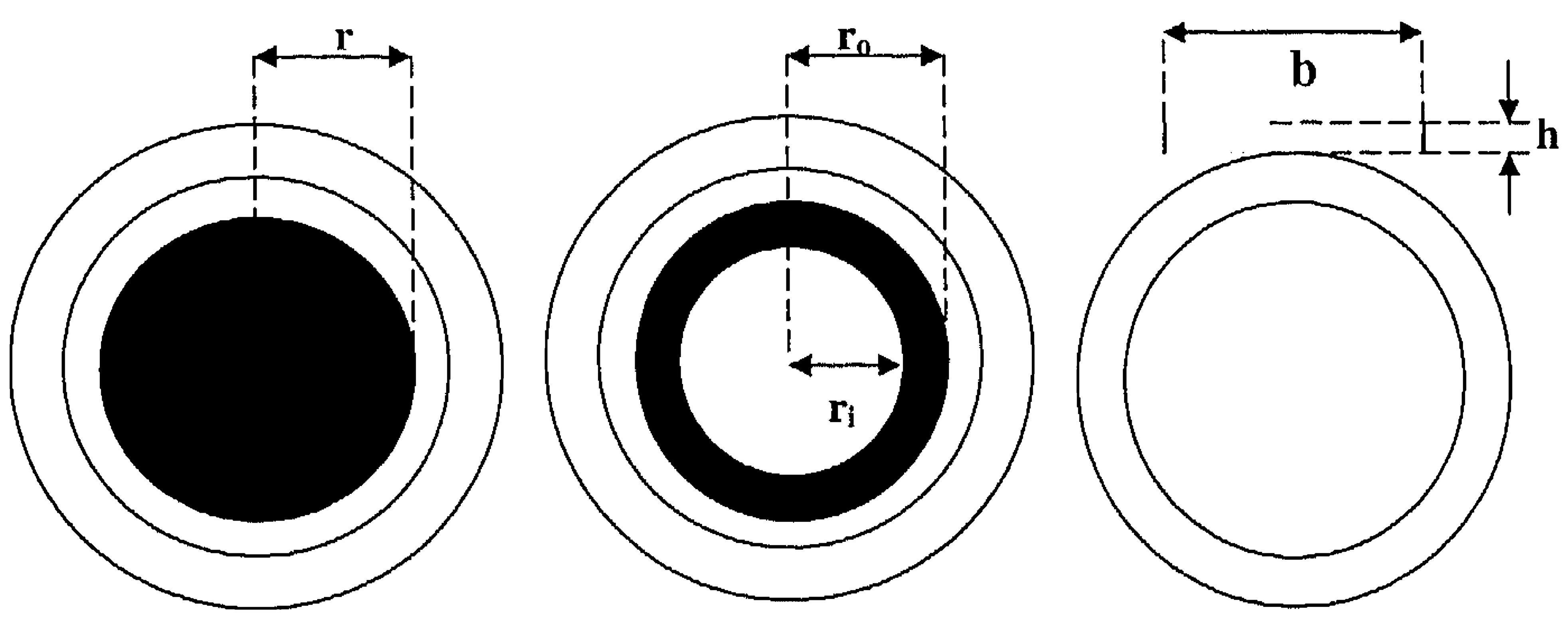
Stiffness: Ratio of load to deformation or slope of the load /deformation curve, indicating how much load is required to deform the object by a specific amount. Units are N/mm, N/deg.

Torsional stiffness: Ratio of load to deformation of a material or structure, when subjected to a torsional load about its major longitudinal axis. The torsional stiffness of an object increases with the shear modulus of the material from which it is made. Also when its polar moment of inertia (which increases when its mass is further from the loading axis) is greater, its torsional stiffness increases. An object's stiffness decreases with increased length. Units are Nm/deg (Newton-meters per degree).

Working length: The working length of an implant is the part of that implant between the 2 fixation points to the bone. Bending stiffness is inversily proportional to the square of the working length and torsional stiffness inversely proportional to the working length itself. With a nail, fixation points are situated at both ends of the implant, leaving a long working length and hence less bending stiffness.

Moment of inertia

Figure 1: Formulas determing second moment of inertia for left: solid rod, mid: tube and right: plate. r = radius, r_i = inner radius, r_o = outer radius, b=base, h=height



$$I_{rod} = \frac{\pi}{4} r^4 \qquad I_{tube} = \frac{\pi}{4}(r_o^4 - r_i^4) \qquad I_{plate} = \frac{b \times h^3}{12}$$

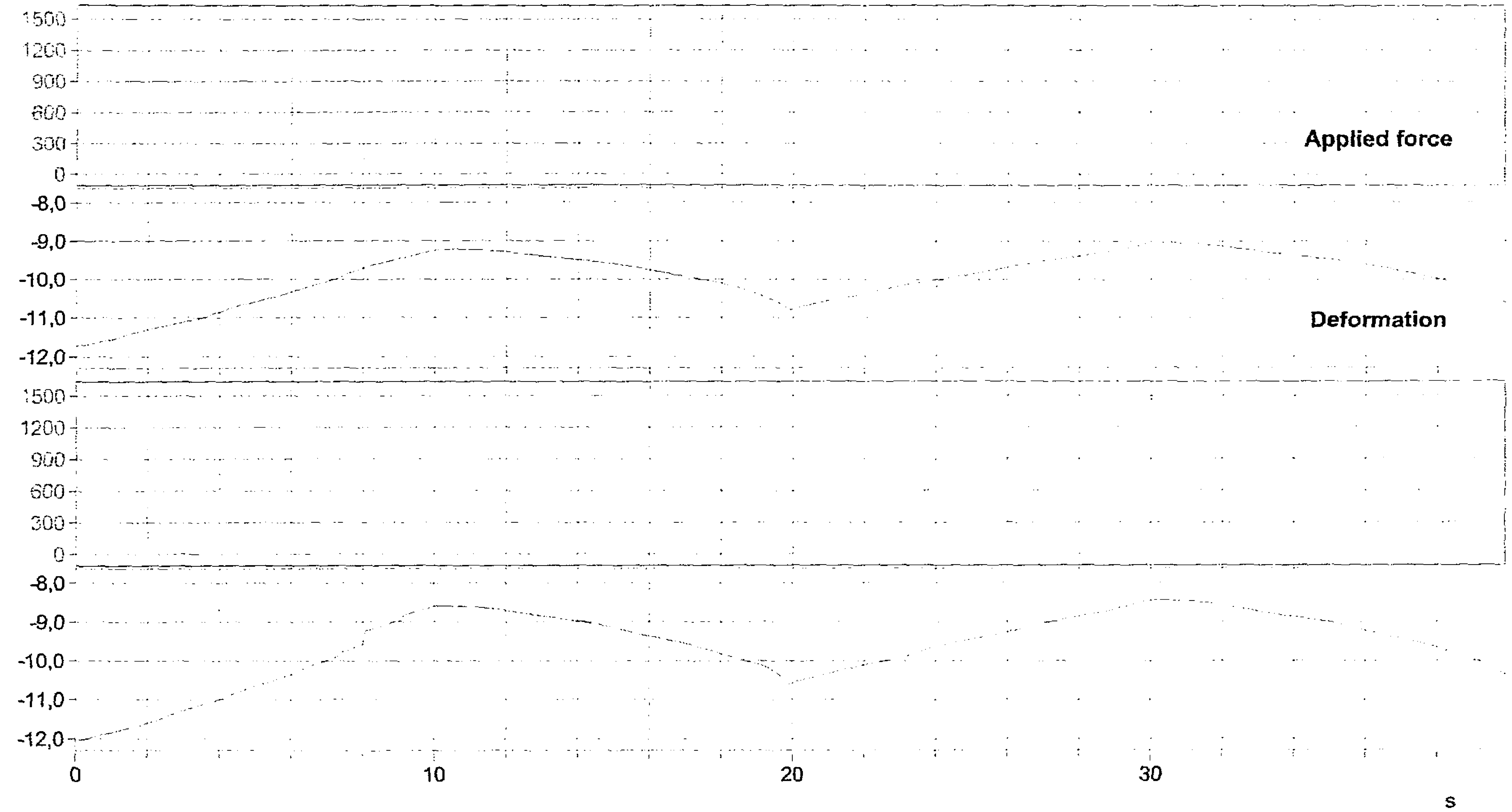
This is a measure for distribution of material round a certain axis of an object and also determines resistance against bending. From the formulas presented in Figure 1 follows that if the cross sectional diameter of a solid nail is doubled, the moment of inertia increases 16 fold . For the plate the moment of inertia is determined through the 3rd power of its thickness. Doubling the thickness results in 8 fold increase of moment of inertia. A solid nail will have a higher moment of inertia then a cannulated nail of the same material.

Projekt: J. Verbruggen	Biomechanische Studie zum Vergleich der Festigkeitseigenschaften von TLN und UHN bei der Versorgung der Humerus-Schaftfraktur mit Kompression	Seite: 133/147	Plot: 09.05.07
Versuchsdatum: 29.11.01	Dokument:	PIKOMP	

Versuch 6:
1500 N Zug

Position / Richtung:
axial

oben: linker Humerus, TLN
unten: rechter Humerus, UHN



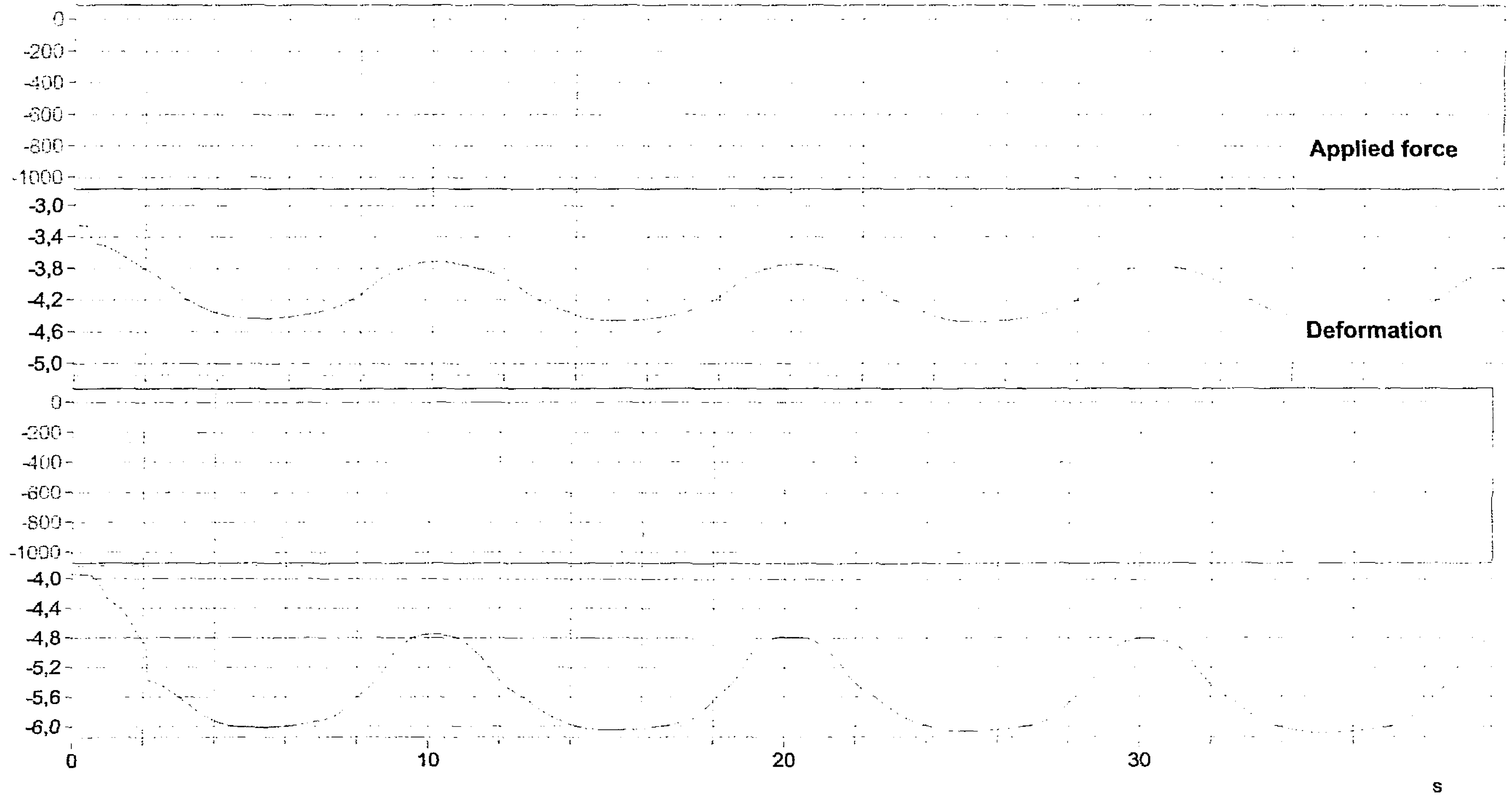
Projekt: J. Verbruggen — Biomechanische Studie zum Vergleich der Festigkeitseigenschaften von TLN und UHN bei der Versorgung der Humerus-Schaftfraktur mit Kompression — Seite: 135/147 Plot: 09.05.07

Versuchsdatum: 29.11.01 — Dokument: — P1KOMP

Versuch 8:
15 Nm Biegung

Position / Richtung:
lateral-medial

oben: linker Humerus, TLN
unten: rechter Humerus, UHN



Projekt: J. Verbruggen | Biomechanische Studie zum Vergleich der Festigkeitseigenschaften von TLN und UHN bei der Versorgung der Humerus-Schaftfraktur mit Kompression | Seite: 139/147
Plot: 09.05.07

Versuchsdatum: 29.11.01 | Dokument: | P1KOMP

Versuch 11:
6,5 Nm Torsion

Position / Richtung:
axial / negativ

oben: linker Humerus, TLN
unten: rechter Humerus, UHN